

Northern Ireland Affairs Committee

Oral evidence: [Future of the Land Border with Republic of Ireland](#), HC 700.

Wednesday 22 February 2017

Ordered by the House of Commons to be published on 22 February 2017.

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Members present: Mr Laurence Robertson (Chair); Tom Blenkinsop; Mr Gregory Campbell; Lady Hermon; Kate Hoey; Danny Kinahan; Dr Alasdair McDonnell; Nigel Mills; Jim Shannon; Bob Stewart.

Questions 466-528

Witnesses

I: Stephen Kelly, Chief Executive, Manufacturing NI; Colin Hayburn, Executive Director, Almac Group; Graeme McBurney, President and Managing Director, Almac Pharma Services.

Examination of Witnesses

Witnesses: Stephen Kelly, Colin Hayburn and Graeme McBurney.

Q466 **Chair:** Gentlemen, thank you very much for joining us. As you know, we are holding an inquiry into the future of the land border with the Republic of Ireland following Brexit, so we are very pleased that you are able to come and give evidence to us. Perhaps I could invite you to introduce yourselves fairly briefly, tell us about your organisation and your role in it, then we can go from there, but thank you very much. Mr Kelly, would you like to start?

Stephen Kelly: Good morning, sir and the Committee. I am Stephen Kelly, Chief Executive of Manufacturing Northern Ireland. We represent the manufacturing sector, particularly on the areas of the cost of doing business in Northern Ireland. Obviously this particular piece of work has added to that workload in more recent months.

We represent 550 manufacturers, ranging from Northern Ireland's largest manufacturer employers down to the smaller SMEs. Manufacturing represents roughly 85,000 direct jobs in Northern Ireland but, with the induced and additional jobs added to it, it is about 214,000, so one in four families in Northern Ireland depend upon a manufacturing wage. Our manufacturers sell in markets at home and abroad. Obviously the issue of the UK's exit from the EU has some concerns for those members, as well as the opportunity to seek out opportunities.

Graeme McBurney: Good morning, Chairman and the Committee. I am Graeme McBurney. I am the President and MD of Almac Pharma Services. We are an organisation that offers contract services to the global pharmaceutical and biotech industry in the area of drug product formulation and licensed drug manufacture and supply. Obviously we are based in Northern Ireland, but our customer base is really from Europe, the US and farther afield into Japan, Australia, Korea and so on. We have about 700 employees in Northern Ireland and manufacture none of our own products; they are all licensed for other companies. Our operational base is centred on Northern Ireland, but we have contract facilities in the US and in Loughborough in the UK as well.

Colin Hayburn: Hello, Chair. Hello, Committee. I am Colin Hayburn. I sit on the holding board of Almac Group, which is the parent company in which Graeme's Pharma Services is located. Almac Group's European headquarters are in Craigavon, Northern Ireland. It offers a range of services to the pharmaceutical sector, from API manufacture, formulation and development, and the manufacturing and supply of clinical trials for clinical trials. It supplies on a global basis to most of the top-40 pharma and top-30 biotech. It has 5,500 staff globally, 2,600 based in Craigavon, Northern Ireland. As I say, our European headquarters are in Craigavon and we have a number of manufacturing facilities in the US, in Singapore and in Tokyo. We recently purchased facilities in Ireland. As Graeme said, we made a significant investment in Loughborough in England.



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Today, we would be keen to explain to you the significance of the current benefits we get from the single market and the customs union. In doing so, I suppose our chief concern going forward would be that any measures put in place would replicate those benefits as significantly and as closely as possible. Any deviations to those issues would have significant detriment to us, as a global distribution business.

Q467 Chair: We are particularly looking at the border and how that will impact on your business, whether it is a hard or soft border, or any of these words that have been used. We need to concentrate particularly on that aspect, as far as we can. In that respect, how would the arrangements we come to on the border impact on your business? I will come back to you again, Mr Hayburn.

Colin Hayburn: Why I wanted to mention that, Chair, if you do not mind, is that the circumstances in which we currently do business will have an impact on the border. We currently do not have a lot of cross-border trade.

Kate Hoey: Sorry, did you say you do not have?

Colin Hayburn: No, we do not have a lot of cross-border trade. If I could explain the nature of our business, it explains the nature of why the border will be significant and why we have recently acquired premises in Dundalk and a company that held manufacturing and distribution licences in Ireland. Our business is with major pharma and biotech. It is a contract-based business; it is not to consumers. Under a contract, we will have to sign up to various fairly rigorous regulatory responsibilities and also distribution responsibilities.

After the vote in June last year, and we were aware that the UK would be leaving the European Union, many of our US and global customers contacted us to ask us what our EU solution was, going forward. We had to address that. Under contract, we have to distribute products under EU regulations in relation to quality and the release of those products into the European market. In Craigavon, we currently ship 84,000 shipments into the European Union per annum. If you do not mind, in a second I will ask Graeme to explain the significance of the regulatory effects of having a European Union presence to distribute those products. We need a European Union presence immediately to satisfy those customers.

I know, and we will probably hear today, that the greatest need we have now is for certainty going forward, in relation to regulations, in relation to the single market and the customs union. However, we deal with customers who are very conservative, who contract us to do maybe four clinical trials a year, so they know that that will bridge the gap between the two years when we have to put in place relevant rules and regulations, after we trigger Article 50. We had to address that now; we had to have a European Union presence.



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This means that we will do all we can to maintain and protect the investment we have in Craigavon. As I said, we have 2,600 staff there. We have invested hundreds of millions of pounds there over the past 10 years, and it is our manufacturing and distribution hub and base. However, we need to be able to satisfy our European Union regulations and contracts. Those customers all ask us if we would still operate under European Union laws and regulations post-Brexit, and there is only one answer we could give there. It had to be “yes”. They would not listen to us saying we are confident that, in two or three years’ time, equivalent legislation would be in place so our distribution and quality regimes would not be hindered. We had to say, “Yes, we will do that”. We will have to operate a dual process for a time.

However, if tariffs are introduced at the border, with that manufacturing of those 84,000 shipments, currently and for the next two years there could be a situation where we have to ship some of those products from the south. Our cross-border trade, instead of shipping those out from the UK, will have to ship them from Southern Ireland. That would potentially mean 84,000 shipments crossing the border. If that leads to tariffs at the border or leads to the fact that we cannot eventually get European release of product from Northern Ireland, we will have to move more operations through the European Union, which is the south of Ireland. It is something we do not want to do. It is something that we will fight hard not to do, but it will very much be driven by our customers. If our customers ask for that European Union solution now, we will have to address it or we will lose out.

Much of our competition has a presence in the European Union and they are already using this situation to say to our customers that we have fought to win, “Come to us, because you will be in a very uncertain regulatory environment and distribution environment for the next few years,” so come to us. We have to act with a European Union presence. If you do not mind, Chair, could I ask Graeme to give some detail as to the regulatory requirements for distribution of product from the EU? It is significant to see whether or not we need to move those products from Northern Ireland across the border to the south of Ireland.

Chair: Yes, by all means, but I am conscious that we need to keep it to looking at the impact of how the border will end up. We are not really looking at the tariffs that would be applied for import/export. That is beyond the range of this particular inquiry.

Colin Hayburn: Could I just mention one other thing then, please, Chair? I am sorry for maybe going on a bit, but these are significant issues for us.

Chair: Absolutely.

Colin Hayburn: The products we move are mostly cold-chain products. That are highly expensive biologics, which are shipped in very regulated conditions, refrigerated conditions, often with a seal on the products.



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These are highly expensive products, which will go all the way around the world for clinical trials in oncology, heart disease and diabetes. When those products cross the border, if there is a hard border and checks at that border, any issues that cause those products to be delayed, any issues that cause those products to be opened, whether that is a refrigerated door on a lorry or seals tampered with on the product, will again lead us to a uncompetitive situation. Our customers will not really tolerate that. They will ask for a solution that is within the EU, so that that does not have to happen. That is a major issue for us from a product perspective, if there is a hard border there. The number of shipments I mentioned at the start is relevant to that because, if that is 80,000 shipments crossing the border per annum, you have an unworkable situation there.

Graeme McBurney: As you will appreciate and expect, no doubt, the pharmaceutical industry is a very highly regulated industry. It is governed by directives. European directives have then been carried into law within the UK, under the Human Medicines Regulations 2012. Those both cover the manufacture of product but, more critically to Colin's point, the badge certification and the release of that product into the market for consumption by a patient. Those regulations for Europe require an individual known as a qualified person, so a registered and qualified individual, to release the product on to the market and take personal responsibility for that, following quite a number of activities they must ensure have happened. The product has to be manufactured against GMP. It is manufactured against the marketing authorisation, so the drug product approval by the regulatory agencies, and the testing has been conducted in a lab within the European Union. That is sort of the critical one for us.

That product movement over the border to the south of Ireland will potentially cause a repeat of that full analytical, qualitative and quantitative analysis to ensure that that certification process can happen to allow Almac to release product into market. Driven by those regulations, we will end up in the route that we must take to get that product to market. As Colin mentioned, ultimately for Almac the best outcome is to have a scenario where the regulations are as uninterrupted as they can be to allow a straight released process. There are tariffs and all the rest of it, but there is the technical aspect of the release of product to a consumer and that is something with which we will need to comply to supply any product into the European Union.

Q468 **Chair:** Presumably you have similar standard requirements for customers that are beyond the EU, in Asia for example?

Graeme McBurney: The US actually does not have that directive requiring qualified person release. Craigavon is an inspected facility by the FDA, the United States Food and Drug Administration. That inspection of us allows an individual in Northern Ireland or anywhere outside the US, following a pre-approval inspection and an EIR standard, to release



product for the US market. However, the requirements of the European Union, governed by the EU directives, require that it must be badge-certified within a lab in the European Union. It is a different regulation and very specific requirements for European-Union-released product and countries harmonised to the EU as well, which are Canada, Australia and so on.

Q469 Chair: Thank you very much. Mr Kelly, this is the last question from me and then I will open it up to other members. Fairly briefly, what would be the main concern of your members with regards to the border and how it may end up?

Stephen Kelly: Chair, you have already heard this morning from just one company about how complex the supply chain and market access are for manufacturing. In many ways, anything that adds any level of complexity to an already complex supply environment adds significantly to cost and to risk. What we have is a scenario where, regardless of whether it is 84,000 shipments per year or whether it is one shipment per day, anything that is a potential barrier to the free movement of those goods has very significant impacts.

We are aware of quite a number of companies that are in a similar environment to Almac, in terms of having to take decisions and having to take decisions now. We are very conscious that there is a two-year process, in terms of triggering Article 50 and the expectation of having a new arrangement and deal by the end of that period, but manufacturers have very large capital investments. Manufacturers need time to plan and ensure they put in place whatever measures they need to ensure their sustainability in the long term.

We are essentially saying two things to you today. One is that remaining in the customs union is absolutely critical, in terms of the manufacturing success of Northern Ireland going forward. Secondly, we know that companies will be making decisions within the next 12 months, not within the next 24 months, in order to give themselves time to put in place whatever new arrangements they have to satisfy their own internal needs. Whatever clarity this Committee can help provide is very much valued.

Q470 Jim Shannon: Gentlemen, thank you very much for coming, and thank you also for all you do for the manufacturing base, as an employer and for your employees as well. We really genuinely appreciate all those efforts that you have made, so thank you very much for that. Over the last period of time, I have been the party health spokesperson here, so I have had an opportunity to talk to some of the pharmaceutical companies that are lobbying us post Brexit on how the regulation will enable them to move from one to the other, in a very simple system. We do not yet know what that system is, as you have outlined very clearly. The issue for us is how we make that happen.

At the last meeting we had of the Northern Ireland Affairs Committee, we



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had the Irish Ambassador Daniel Mulhall and I think he was quite positive in his presentation of where the difficulties were, but also how he saw the system work. The Republic of Ireland is in direct contact with all the other EU countries as well, so there is obviously a lot ongoing. His initial presentation to this Committee was quite positive, and that would certainly give you some heart on where we are going. I am asking, first of all, if you have had any opportunity to talk to the Irish Government to see what their direct ideas are hopefully to have that seamless, transparent, frictionless border taking place, which the PM wants to see and I think everybody on this Committee wants to see as well. Have you had an opportunity to discuss it with the Republic of Ireland Government at all, first of all?

Colin Hayburn: We had good conversations with IDA at the time when we needed the facility in Dundalk. We have not engaged specifically around border issues, and one of the reasons we have not was an uncertainty on our part as to who to talk to, because we do not know if the Irish Government will decide on border issues there or if it will be the European Union. We do not know, but we are more than happy to talk to anyone about the real-life issues that we will face on a daily basis. We can do that; we were just not sure who best to talk to.

Q471 **Jim Shannon:** I get the impression, and it was certainly my impression from him when he was here, that the rest of the EU countries understand the Republic of Ireland's particular circumstances. Therefore, the hope would be that there will be a much less degree of difficulty when it comes to crossing the border. You will probably be aware of this through your knowledge of business in Northern Ireland, but I have a number from the agri-food sector in my area and one pharmaceutical company, which is Eakin at Ballystockart. You are a fairly big employer, but they also have factory sites in England and the UK, which helps. I was interested in what you said about refrigeration. The agri-food sector seems to have indicated an administrative method whereby a lot of the paperwork is done beforehand. Then, when it comes to crossing the border, there is probably a fairly seamless crossing, so it will not be delayed too long. Are you aware of that at all from any discussions you have had with the agri-food sector?

Colin Hayburn: Again, no. Our preference, Jim, would be not to need to ship product across the border. That would be our key issue here, you see. We have a manufacturing base and a distribution base in Northern Ireland. It is not ideal for us to have to transfer product across the border. Ideally, we would not do that. We will have to facilitate that and plan for that, but it would not be our key ideal scenario. I know this may not strictly be relevant, but it is relevant enough for cross-border issues.

Why we had to look at operations in the south of Ireland, even before Brexit, was because of a recent ruling from HMRC that we could not reclaim VAT on behalf of our non-European customers. There is a ruling



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in which HMRC changed their position so that, unless you legally owned product, you could not reclaim VAT that was paid on imported product into the United Kingdom. The south of Ireland had a different approach to that. That is a fairly significant issue for our customers. We used to reclaim VAT and take all the burden out of them importing product for clinical trials. Now, our customers again asked us to find a solution, so that we could reclaim VAT on their behalf. Our view to HMRC had always been that you did not need to own the product; you just needed to have a legal interest in the product, and that would be supported by the Government in the south.

We met the Revenue Commission in the south and they allowed us to reclaim VAT on behalf of our customers, which is why we are bringing product into Southern Ireland at the moment. We are bringing it to Craigavon to perform services on and shipping it out of southern Ireland again, so we can reclaim VAT. Again, we have made representations to the HMRC on this, but we find that a ridiculous position. Our customers can still reclaim VAT, but it takes them a longer period to do it. There is currently an appeal on at the moment on our position with HMRC, but that decision has again meant that we are putting shipments across the border on a daily basis.

Q472 **Jim Shannon:** I have a third question, Mr Chairman. This is the last one, because I am very conscious that other people want to speak as well. I think you said you have 2,500 workers in Almac. Is that correct?

Colin Hayburn: There are 2,600.

Q473 **Jim Shannon:** Can I ask you if, within that workforce of 2,600, they are all locals or do you have any EU nationals who are working in your factory? It is just to get a flavour of what you are doing, because I want to understand their status as well. At a meeting that I was at earlier, there was an indication that the Prime Minister was very keen to see the EU nationals protected, and I am very supportive of that. I just want to get your thoughts; does that affect you as an employer

Colin Hayburn: Very much so. We had a lot of panic in our company from EU residents at the time of the vote. We currently have 30 nationalities working at Craigavon from all around the world, including 18 countries from the EU. We have 410 workers who are EU residents working in Almac. We have been talking to those workers about registering for status to have indefinite leave to remain. Again, that is only relevant if you have been there for five years. If you are under five years, as I understand it, you cannot claim indefinite leave to remain. Yes, it is an issue. Clarity around the security of EU nationals is a fairly major issue for us. From a cross-border perspective, we have 30 staff who live in the Republic of Ireland and cross the border each day to come to work in Craigavon. We also have a facility in Athlone, a fine chemical manufacturing company, and again there are staff crossing back and forward between Craigavon and Athlone on a weekly basis.



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Q474 **Jim Shannon:** The reason why I make the point about the meeting I had before, Mr Chairman, is that the Prime Minister's statement of 2 October 2016 said very clearly, "Let me be absolutely clear: existing workers' legal rights will continue to be guaranteed in law, and they will be guaranteed as long as I am Prime Minister." There is a willingness amongst everyone to ensure that workers' rights are protected. I know I could assure the workers in my constituency, those in the agri-food sector, those who have come in and stayed and worked and married and bought houses and are established, but also have a certain level of concern about where they are. I think it is important that the workers are assured of that. I know I have done that with the ones who I have spoken to back home.

Stephen Kelly: Can I come back on that? Almac's experience is very common. What we have discovered, talking with firms since the summer, is that firms are struggling to get people to move to Northern Ireland. Some people are leaving and returning to other parts of Europe or indeed crossing to the Republic of Ireland, and that is for two reasons. The first is the devaluation of sterling has meant that it is not as profitable or attractive in terms of either of coming to Europe or staying in the UK. That is a very real issue for people. Secondly, people actually do not feel welcome.

The more Members who can say what you have just said, the more people who repeat what the Prime Minister has said, the more Members in this House, in the media and elsewhere who actually remind those people who are making a very positive contribution to our manufacturing firms in Northern Ireland and elsewhere that they are welcome, that they are making a valuable contribution and that we want to continue to welcome them, would be very worthwhile. A very strong message on that, coming from this House and elsewhere, is something that we would very much welcome.

Jim Shannon: Very quickly, I would just say that that is a point that I have certainly made in my constituency, and I think it is very important that, coming from the highest level, from the Prime Minister right through, there is a commitment to the workers to ensure that they have rights and their legal rights are protected. It is very important that we do that individually, and that you as employers are assured of that as well.

Q475 **Kate Hoey:** Is the reason that you have so many people from other EU countries because you cannot get people in Northern Ireland with the skills? Are you occasionally turning down a Northern Ireland person or a Republic of Ireland person because the skills are better from there? Why are you having so many?

Stephen Kelly: It is twofold. One is that the skills are not available, so a lot of our employers would employ people with very particular skill sets that may not have been available. They may not have been trained; there may not have been other opportunities to develop those in other firms, either in Northern Ireland or in the UK for the matter.



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The second thing is that people do not want to take some of the jobs that some of these foreign nationals are taking. We do not have a situation where employers are choosing to pick foreign nationals over people from Northern Ireland. That simply does not happen. Employers will employ anybody who will do that job, provided they can do it in a productive way, they turn up for work and they get on and do that job proficiently. We are not aware of any situation where an employer will decide to pick a foreign national over a local person. That simply does not happen.

Q476 **Kate Hoey:** They are all high skills, not low skills.

Stephen Kelly: There are both.

Colin Hayburn: We have a serious skills shortage in analytical chemists and formulation scientists, and also IT skills in bioinformatics. There is a major shortage here. We are trying an outreach campaign with local schools and universities here to get local staff and we cannot get them, so we have to recruit from France, Germany and other countries within the EU.

Kate Hoey: I understand that, but the low-skilled jobs I do not, if there are people unemployed in Northern Ireland, claiming benefit, and there are jobs going.

Stephen Kelly: There are a number of reasons why people do not choose to take those jobs as well. We have occasions where the benefit system is actually prohibiting people from taking some jobs. We have examples of employers who have offered staff overtime, bonuses, additional hours and additional wages, and they have turned them down because they may be on some level of benefit, believe it or not. This argument about raising wages and so on needs to come alongside the benefit system.

Q477 **Kate Hoey:** That will presumably all have to change when Brexit happens.

Stephen Kelly: Potentially it will but, just to be absolutely clear, there is no employer in Northern Ireland choosing not to employ somebody from Northern Ireland.

Q478 **Danny Kinahan:** May I echo what Jim Shannon has said? I am very grateful for all the work you do for Northern Ireland. As we are talking about skills, the border, and research and development, you have a linkage with Queen's and other universities. How do you see that and what difficulties does it raise in not just the skills, but the professorships, and the linkage that goes on when people have to move backwards and forwards across the border?

Colin Hayburn: We have a number of research collaborations with the Royal College of Surgeons in Ireland, UCD and Trinity. We have a number of funded research positions at Queen's, which we fund directly. They have accessed IMI joint funding for those academic industrial positions.



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We have not heard of any downside to that at the minute. In fairness, we have not, so we do not know if that is affected or not.

Q479 **Danny Kinahan:** It is an unknown. You are talking about 80,000—I cannot remember exactly what—moving across the border. How much is exactly going the other way to the States, to Japan or to Singapore?

Colin Hayburn: From Craigavon there are only 10,000 rest-of-world shipments, but we have facilities in the US, Singapore and Tokyo, and there will be shipments from those facilities. Craigavon is primarily our EU headquarters, which deals with EU countries. We certainly have shipments to the US and South America, which will be handled from our US operations. Tokyo and Singapore will handle most of the eastern operations.

Q480 **Danny Kinahan:** Is that 10,000 shipped across the border to go to the rest of the world or does it go to the rest of the UK?

Colin Hayburn: It is probably not, and other things are relevant there about shipping chains, airlines, approvals and where they are going to. When you ship a product into a country in which we have no presence, we need to have an importer of record in that country and we need a customs broker in that country, so it all depends on what airline and what approval network they have in place. That will trigger whether it is shipped out of Belfast, Dublin or has to go through Heathrow. That could be a relevant factor.

Q481 **Danny Kinahan:** If we are to look at expanding in the lines of Brexit to the rest of the world, that work is not going to be for Northern Ireland; it is going to end up being from the States and other places.

Colin Hayburn: That might not be affected. Those 10,000 shipments might not be affected like the European Union shipments, those 80,000 shipments. We have no desire for those to have to be manufactured elsewhere than in Northern Ireland. It would not be ideal in any way. In the short term, if there is no clarity around our position there, particularly if that two-year window to put in place relevant legislation passes, there is nervousness there among our customers in relation to what the future looks like. We might be forced to have more of an operational presence in the south, because of our need for EU operations.

Q482 **Danny Kinahan:** The comment we got from Michael Lux two weeks ago was that the transitional arrangements might not be two years; they will be 10 years. That means 10 years of uncertainty. To you does that mean 10 years of people being shy of staying in Northern Ireland?

Colin Hayburn: No, it will not, because we cannot wait for 10 years. We have to act now. We have acquired premises in Dundalk and acquired a company. We made that decision two weeks after the Brexit vote, because we could not wait. We were asked by our customers, major pharmaceutical companies, "What is your solution to have an EU



offering?" We cannot say to them, "We do not know", or "Wait and see". We have to say, "Here it is".

Q483 **Danny Kinahan:** Can I ask Stephen how much of that you are seeing from other manufacturing companies?

Stephen Kelly: The first phone call I had about the potential to find another manufacturing location came before 8.00 on 24 June. We understand that politics, civic life and public life move at a particular pace, and that this is a very difficult and painstaking negotiation that lies ahead, but manufacturers work at a completely different pace again. Particularly when you are making big capital investments, where you can find that funding to make sure that you have that sustained future, where you choose to place that capital investment and where it is least at risk are conversations that take place either formally through the larger organisations and their board structures or informally in the very many small family-owned manufacturing firms that we have.

We are aware of a number of firms that are actively seeking other locations, not just in Europe and the EU, post the UK's exit, but also on mainland GB for that matter, as well. The potential for any stops or checks at borders makes it difficult for them to ship product from Northern Ireland into the GB marketplace, so those conversations are happening all the time. Are they taking action as quickly as Almac? They are probably not; however, those companies are running through their normal PESTLE analysis, will understand where those risks and opportunities lie for them and will be taking action accordingly.

The counter to this is that they are actually opportunities from this, in terms of receiving investment in Northern Ireland. Whilst we are aware of firms that are actively looking to ensure that they are not the wrong side of the border, the UK is still going to be a very attractive marketplace. The UK is 60 million consumers; it is one of the largest economies in the world. That is a very attractive marketplace for European manufacturers as well. We are aware of particularly one firm that was certainly on the radar from the European headquarters, because of the cost of doing business particularly around energy, prior to the vote on 23 June. Their position has become more concrete since that point, because the headquarters understand that at least they have that presence within the UK market, post the UK's exit from the EU. This can have a play both ways.

We have been articulating more recently that Northern Ireland, in terms of its FDI potential, could probably have an equally good opportunity in Liffey Valley as it does in Silicon Valley, where there are firms that are keen to ensure that they have access to that UK market post 2019.

Q484 **Danny Kinahan:** Are you getting a chance to put your point across to Brexit teams here, when we do not have an Executive at home, or are you finding that you are being left out at the moment?



Stephen Kelly: That is a very good question and very useful question, actually, Danny. Like others, we attended the all-island dialogue on Brexit on Friday, in Dublin. It was a very interesting experience. There were certainly a lot of issues, concerns and worries, which formed pretty much the first two-thirds of the day. What happened in the last third was probably the most powerful piece of that whole day's experience. For instance, at one moment you had the Minister for the Economy sitting alongside the chief executives of IDA Ireland, Enterprise Ireland, Science Foundation Ireland, InterTradeIreland, Tourism Ireland, Bord Bia and all those major business and economic development agencies.

You really got the sense that there was one single-team approach to actually dealing with the challenges that Brexit brings for the Republic of Ireland, but also collectively looking at what, if we are going to lose something, we can win and gain on the other side. There was certainly a very positive attitude there that Ireland is poised to benefit from this and we will seek out those benefit opportunities as quickly as possible. Just the optics of having all those chief executives with the Minister and the Prime Minister of the country there at the one time sent a very powerful message to the people who were attending.

If you counter that with what we are experiencing in Northern Ireland and indeed in a UK context, there is no sense that there is a single approach to all of these issues. No one is really sure who to talk to. You have already heard Almac's own experience about where they turn for information and so on. Frequently now, we are using some of the information that the Irish Government are presenting or some of those agencies, whether they are ESRI or others, to point some of our manufacturing members who have some concerns to try to get some clarity around some issues, whether those are tariff issues or whether they are country-of-origin issues. There seems to be a lot more information, a lot more dialogue and a lot more engagement, certainly with the business community, through those all-island dialogue mechanisms. They have had 14 different sectoral group events that firms have been invited to, and sadly we are pointing people to some of that information because the information flow is not coming, either from the Departments or the Executive in Northern Ireland, nor indeed from Westminster.

Q485 **Dr Alasdair McDonnell:** Thank you, gentlemen, for your evidence so far. Again like others, I want to thank Almac. I know Stephen and I know the job he does, so it would be superfluous for me to thank him for the work he does, but I want to thank Almac for the tremendous job that you do for Northern Ireland and for the pharma industry. What I wanted to look at briefly was the whole question that you have told us that about 30 people move from south of the border. Could you perhaps tell us in some detail—and I know it is hard to speculate—how the Dundalk facility will function? First, will you move people from Craigavon to Dundalk to man that operation? How do you see that evolving? Secondly, we have already dealt with personnel terms. How do you see it evolving in terms of



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function? I am not trying to get, and I know that you would not volunteer, anything of commercial sensitivity or detail but, in exporting your products and trials, will you still do the testing in Craigavon and wash it through Dundalk? How do you see that facility working? I think the devil is in the detail of some of this, in terms of other companies.

Colin Hayburn: It is not an easy question to answer. We see the operational requirements of Dundalk being fairly minimal in the short term, because we do not need to fully utilise it at the moment, because of our existing contractual arrangements. It is really a safety net for us, at the moment, from an operational perspective. If we do need to use it, we can use it. We can make it operational relatively quickly, in relation to release of product and in relation to distribution of product. I would say it is fairly minimal in the short term, Alasdair, but with the capability of ramping up if we have to. It would principally be product release and distribution from that facility. We have no desire to change our commercial base from Craigavon, from an investment perspective and a staffing perspective. It would be the wrong thing to do, but we have to respond to what customers need and want. The facility allows us the room to do that, if we have to.

Q486 **Dr Alasdair McDonnell:** That has broadly answered the question, but do you visualise moving people?

Colin Hayburn: We will possibly not be moving people. The beauty of Dundalk is that it is only 45 minutes away from our facility. We will probably recruit. We will certainly have to recruit staff this year and I would say there will be local recruitment of staff there. There will be some cross-movement of staff from Craigavon, but it will be relatively small in the short term, Alasdair.

Q487 **Dr Alasdair McDonnell:** I suppose the bottom line for all of this is whether you see much of a threat to your function, operation and employment levels in Craigavon. Are you telling us indirectly that to meet the demands of your customers, you may have to scale down at Craigavon and scale up in the US or scale up somewhere else?

Colin Hayburn: No, I would not say so. The situation will become more of a challenge in relation to the legal situation and regulation in the EU. If we can get a set of laws that is equivalent to our existing EU laws, in relation to release of product and customs harmonisation, and if that can happen smoothly, we should be fine. There will be a certain period of uncertainty in the interim, but I think we can manage that. If those laws or regulations are out of line with the EU that will be a difficult situation for us. Our customers will find us difficult and they will ask for more of an EU-compliant system of dealing and we will have to respond to that.

Stephen Kelly: Could I maybe follow up on that? We know that the British Irish Chamber of Commerce have said that 100,000 GB firms have lodged or registered a company in the Republic of Ireland since June of last year. There is no expectation that there will be 100,000 new



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factories, new offices and so on. In many ways, these are hedges against worst-case scenarios, should they develop. In a broader sense, in terms of the Northern Ireland manufacturing community, it really depends on a business-by-business basis, where their customer is and whether it is in their interest to be on the other side of any potential EU border or on the UK side of that EU border.

What it is doing is making investment decisions more uncertain, because people are waiting to see where they should make this investment decision. That uncertainty is driving hesitancy from making those investments, which ultimately leads to a lower business performance. When firms that are as organised and as equipped as Almac do not know that they cannot afford to do that, many other smaller firms are waiting and seeing.

Now, if we know that there are 100,000 UK firms registered in the Republic of Ireland, my argument would be that many Republic of Ireland and many EU firms for that matter are registered in Northern Ireland, as their potential hedge. What are we doing to try to make sure that we can recruit those investments from outside the UK that want to ensure that they have a presence and access to the UK marketplace? That is going to be critically important going forward in terms of our own economic development.

Can I just make a point about the staff? I have had a couple of interesting conversations with some of our larger employers. Seagate Technologies, in my own city, made a £1.5 billion investment. They employ about 1,400 or 1,500 people. They have begun surveying what Brexit potentially means for them. Some 20% of their staff come from Republic of Ireland and travel across each day, and that is very significant for them, because these are very highly skilled people, some of that at PhD level, who are very hard to find internationally, never mind on your doorstep. Other firms are in the border area. One particular firm, Quinn's, has 48% of their staff working on one side of the border but living on the other side. That business is a completely cross-border business, so that would be expected.

What this is beginning to tell us is that firms are needing to be tooled up, needing to be informed, ready and understand what potential opportunities and risks are there. What we heard on Friday from Bord Bia, which is the Irish international food marketing board, is that they have actually produced a Brexit toolkit for their firms and they are beginning to take firms through it. It has been developed alongside PwC. Tools like that are going to become increasingly important to give confidence and to give certainty to firms, as they make those investment decisions. It is something that I think would be very worthwhile, either as a UK Government or our own Northern Ireland Government. Actually developing similar kits would bring some clarity to people.



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Frequently, we would talk with companies that think they potentially have a big issue with Brexit but, whenever you really drill down through it with them, the issues are less apparent. Those are people who work intimately with their own businesses, and they are beginning to not really understand the impact that this may have or not have, for that matter. That kind of Brexit toolkit product developed by someone, whether ourselves or we may end up purchasing that ourselves alongside PwC or others, would be something that is very valuable to firms to bring that certainty for them.

Q488 Mr Gregory Campbell: Like others, I welcome your presence. My colleague and former member of the Committee, David Simpson, constantly tells me of the good work that Almac does in his area, in Upper Bann. You have talked quite a lot about the uncertainty. I can fully understand the business need for more assurance and more certainty. That is the environment in which business thrives. Equally, the converse is that uncertainty has negative implications. Of course, even supposing the uncertainty of what the EU itself will look like in the next few months, because there are elections in a number of countries over the course of the next few months, so we do not even know what that is going to look like on the other side of the coin, I am interested in Mr Hayburn's comments on competitors. Are you aware of any competitors in the Republic of Ireland that would be supplying the UK market, in a major way, which may be faced with similar problems that Almac could be faced with, on the other side of the coin?

Colin Hayburn: There are not in our sector. Our competitors would have facilities in EU countries, not in the south. We are not aware of any competition in the south, but they are certainly making a lot of mileage of the uncertainty that we will face in jurisdiction, compared with their security in the EU.

Q489 Mr Gregory Campbell: Are the other competitors in your sector that are supplying into the UK market in France and Germany?

Colin Hayburn: They are from that region, yes.

Q490 Mr Gregory Campbell: I presume that they would be making representations. If Brexit is going to work, it has to work in a two-way process; tariffs are a two-way deal and everybody knows that. Are you aware of representations being made?

Colin Hayburn: No, I am not.

Q491 Mr Gregory Campbell: The other thing I am interested in is the wider cross-sectoral format. I know Stephen from a previous life. Do you detect a change? I can well understand, post 23 June, there was a big interest with people hedging their bets, as it were. I understand that, but we are now eight or nine months on. In the recent weeks and months, say since Christmas, have you detected that people are now beginning to make adjustments, or is there still the same level of uncertainty that there was nine months ago?



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Stephen Kelly: I think people are beginning to really understand some of the potential implications from this, which is actually firming up some views and opinions that may lead to certain decisions. There is some clarity that exists around what potential border mechanisms will mean, in terms of their business and the implications that they have. From an InterTradeIreland survey, only 91% of firms on the island of Ireland had any experience of dealing with a tariff environment. You can imagine that, as a smaller exporting community, our Northern Ireland numbers would probably be higher than that.

We have actually been speaking with some firms, and I have some evidence here for the Committee today, on just what that country-of-origin certification and the paperwork around that would actually mean in terms of cost to an individual business. Between the development and the time required to produce those certificates, plus the letters of credit from banks that are required to export alongside, the total is £478 per shipment. That is roughly the same price as shipping a container from Northern Ireland to GB or two-thirds of the price of shipping a full container from south-east Asia to Northern Ireland, for that matter. That £478 admittedly has staff time included there, because a lot of this is manual at this point. Even if some of that were made digital, it only knocks about £51 off that, so it is £400-plus per shipment for each one that goes out and potentially for each shipment that comes in as well.

The implications that that has for our exporting firms are pretty profound, to say the least. The reality is that those are the sort of costs that firms will try to avoid, plainly and simply. We are already at the end of every pipeline in Northern Ireland, whether that is for energy or for gas, at the beginning and the very end of the supply chain, being an island off an island off a continent. People will take steps to avoid those additional cost burdens being applied to them.

Q492 **Mr Gregory Campbell:** I have just one more, Mr Chairman. It may be in some of the evidence that Stephen referred to. Have you any information or experience external to EU countries, in terms of accessibility difficulties and the ease with which you have been able to trade, on either side of the equation? Some evidence of that could be fed in so that we can see what a post-Brexit best-case and worst-case scenario might look like. It could certainly inform opinion in terms of what we would like to see two years from now.

Stephen Kelly: We would certainly say, in a more general sense, from talking to firms that are exporting, the reasons that they find it difficult to export is not that they have had difficulties getting access to that market. There are many different cultural, business, language and cost reasons why they have not done that. More relevant is Almac's own experience selling globally and what that has been like for them.

Colin Hayburn: If you sell into the European Union it is fairly streamlined and fairly straightforward. Selling into somewhere like the



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US, even if we ship product between our sites from our facility in Craigavon to a facility in Pennsylvania, we still have to ship it as if it is a commercial product. The forms, the bureaucracy and the checking of the country-of-origin credibility and traceability of those products, the tariff work you have to do to match up the product per tariff—and there are complicated tariffs there, depending on whether your drug is active or a placebo—need a full team to be engaged to do that. The bureaucracy is more expensive. You have more staff costs per shipment than you would have into the EU.

If we replaced our EU customs union system with a system like that, it would not be good for us. It would be highly uncompetitive for shipments within the European Union. If there is any way we can harmonise and make equivalence with the existing laws to make the shipments the same that is our ideal scenario. If we have to go to a system like us shipping product to the US, it would be harmful for us. It would make us uncompetitive.

Stephen Kelly: That is the critical thing for us across all the manufacturing sector. There is talk of a frictionless border but, at the same time, there is talk of whether the solution to provide that would be electronic. To me, “frictionless” means the absence of any friction. If you include even any requirement for paperwork, country-of-origin certification, lines of credit and so on, even if it is electronic, even if it is just cameras on borders or little nodes in vehicles that track vehicles going forward and back, it is friction. That creates more complexity to an already complex supply chain and distribution chain.

As I have said, that £478 per shipment, as a guide, for a customer outside the EU, is currently something that is not welcomed by any manufacturing firm, whether those firms are shipping outside of the UK or those firms—and that is the vast majority of firms—that are importing goods to Northern Ireland. Some 54% of our exports go to the EU, and 74% of our imports come from the EU. Three-quarters of the raw material that we will be using will potentially have additional costs applied, because of that need for customs and country-of-origin certification requirements.

Q493 **Chair:** From that, given that the EU obviously has an interest in this, it goes back a little to the point Danny was asking. Are you able to have these conversations? Her Majesty’s Government do not want a hard border. The Republic of Ireland do not. Politicians in Northern Ireland, when they are up and running, will not want it, but there is one extra body involved in this and that is the EU. Are there any ways you can put your views forward to the negotiators in the EU, because they are the ones who can make this all very easy or very difficult?

Stephen Kelly: We are making that very clear. Just so we are clear as well, we are not talking about any hard border or soft border or any electronic border. Any border adds complexity, which adds costs, which actually damages the sustainability of firms. Will there be a requirement



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to do this? It will have to be an EU border, as a minimum, but it is potentially also going to have to be an HMRC border, depending on what goods have been imported in and depending on the deal that happens at the other end of this negotiation.

From our point of view, things like the common travel area are easily resolved. That is almost a given for us, in many respects. We are positive about things like a trade deal with the EU and free travel. There is then the potential there for a trade deal; I have no doubt about that whatsoever. The thing that will most damage us and most damage the manufacturing sector in Northern Ireland is leaving the customs union and, with that, the requirement for country-of-origin certification, lines of credit, border checks and so on.

Q494 Lady Hermon: Just following on from that point, if we did have—and we do not have—the Prime Minister here or if you were in a meeting with the Prime Minister, what would be your priority list? What do you need guarantees in relation to from the British Government, in order to preserve and indeed increase manufacturing in Northern Ireland? I am really concerned by your evidence earlier today. There is uncertainty out there. It is obviously having an impact, so what do you need to hear from the Prime Minister?

Colin Hayburn: Lady Hermon, those items that we mentioned, access to the single market and equivalence in relation to the customs union, I know might be an ideal, but we have thought about this and that is the only answer we can find. We do not want a system that changes this and makes it more difficult for us to distribute product in the European Union, if it makes it costlier, if it makes it more cumbersome, if it makes it unattractive for our global customers. Most of our studies are global studies now. You have European markets, and you have global markets and US markets, but a lot of our studies are global now. We will be harmed if the European Union aspect of that is more cumbersome than it ought to be. Just to reflect what Stephen has said, the customs union is vital for us, for cost and for operational smoothness and, to Graham's point earlier, equivalence in relation to release of product from the UK into the European Union to make the legislation as seamless as it is now is vital for us.

Q495 Lady Hermon: Have you had an opportunity to make these points to the Secretary of State for Northern Ireland?

Colin Hayburn: We have not directly. We have met with him. From memory, I think we have, Lady Hermon. We have made those points.

Q496 Lady Hermon: Did you make them directly to the Secretary of State?

Colin Hayburn: We are struggling to know how to express those points, even in the evidence we have given today. Do we submit a written submission to this group that gives more robust, detailed evidence to say what we really need to be addressed?



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Lady Hermon: Absolutely.

Colin Hayburn: We talk here. We talk to the Secretary of State. Sometimes you leave that meeting unsure what happens next.

Chair: You are very welcome to submit written evidence as well, yes.

Lady Hermon: It could be written evidence and oral evidence, all of it.

Colin Hayburn: We heard about this hearing on Friday, so we did not have a lot time to prepare for it. We do need to find a mechanism where we can get our voice heard. They are realistic non-political issues we are bringing up here. They are just issues we have to maintain our business in Northern Ireland. How best do we put that case forward? How do we know if our case has been listened to? Who else should we talk to? That guidance would be very welcomed.

Q497 **Lady Hermon:** I think it was Stephen who mentioned the Brexit toolkit, which is available in the Republic of Ireland, well in advance of the triggering of Article 50 by the UK Government. It would be helpful; I picked up on that message. Can I just ask you, Colin, if I may call you Colin, you mentioned VAT earlier and how helpful the Revenue Commissioners were in the Republic of Ireland? I am sure you will be aware that there has been recent coverage of the Revenue Commissioners in the Republic doing some contingency planning, which included identifying possible locations for custom posts along the border. At that stage, having had a good working relationship with the Revenue Commissioners in the Republic of Ireland, did you lift the phone to anybody and say, "What on earth is going on here?"

Colin Hayburn: No, we did not. We can only do one thing at a time, Lady Hermon, so no, we did not.

Lady Hermon: Did it cross your mind at the time though?

Colin Hayburn: To be honest, it did not. The VAT was a major issue for us. The fact that we could reclaim VAT on customer product was a highly valuable benefit for those customers. The fact that that was taken away from us and we had to look at the Irish commissioner to find a solution for that we could not understand. Coupled with Brexit, it made the United Kingdom more uncompetitive and it seemed that we were doing all we could to be less business-friendly. We could not understand it. I know that there is an appeal going on at the moment in relation to that ruling, but our biggest priority was addressing the requirement to be able to satisfy our customers.

Q498 **Lady Hermon:** In light of the events, and how critical you have explained to us it is that shipments of your goods have to go through the Republic of Ireland, if we came out of the customs union with all of the paperwork and the additional cost, do you think it might be worth your while perhaps exploring a little bit further what the Irish Revenue Commissioners are actually planning and how serious they are about this



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contingency planning?

Colin Hayburn: We will certainly talk to them, yes.

Q499 **Lady Hermon:** Do you mind if I could come back to you, Mr McBurney? A point you were making earlier on in your evidence was about the need for certainty. You are dealing with fairly high-tech and very complicated pharmaceutical products, which are essential in critical operations that save the lives of thousands of people around the world. You have a wonderful business. The Prime Minister and the Brexit Secretary have assured us that the great repeal Bill will absorb all EU legislation and all EU case law, the directives and the regulations, when we leave. The great repeal Bill, which will come through this House, will absorb all of that EU legislation. Does that give you some sense of reassurance?

Colin Hayburn: I suppose that the timing of that is the main issue for us, so I agree with you.

Q500 **Lady Hermon:** Elaborate on the timing. Is it because it might be too long?

Colin Hayburn: We are dealing with customers that are very conservative. The pharmaceutical industry is very conservative. It does not change its processes quickly. If it is an established way of dealing, it does not change quickly. They will not have a lot of patience with us if we say that we do not know what we are doing.

Lady Hermon: You will lose out to your competitors if you cannot give them a guarantee.

Colin Hayburn: We would immediately. We will sign up to a three- or four-year study. You pitch for that work; you win it. You are tied into that study for four years and maybe with a customer for a number of studies, so you set up operational procedures that mean it is easier for that customer to deal with you. If we are seen as not competitive or uncertain, in relation even to things like the handling of data for a clinical trial—the EU has a harmonised system for the submission of data for a clinical trial—if we are outside of that, we are uncertain about the data that is generated from a clinical trial. Can it be part of the submission for approval of that drug? If that is uncertain, some other pharma company would just say, “Go to a competitor”. They will not tolerate any uncertainty or hesitancy in relation to that, because it puts their \$1 billion study at risk, so they will immediately go to a customer. We have to address all of this.

Q501 **Lady Hermon:** Sorry to interrupt. That is the second time you have actually said that their decision-making will be immediate and they will go immediately.

Colin Hayburn: If we do not win that work, they will go to a competitor. We will not get in to talk to that customer again for maybe another three or four years, so we have to address this problem now. I would have



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confidence that, eventually, there will be some form of equivalence and those laws. I would have confidence in that. However, we cannot wait.

Lady Hermon: Yes, and you cannot offer that guarantee at present.

Graeme McBurney: No, it is not there. When we talk about the release of product, Lady Hermon, that is the release of every single batch of product we manufacture, every shipment we make. That needs to be released into the market. It goes to Alasdair's point earlier on our Dundalk facility and our investment down there. We have moved to have a presence close to the border and we have bought a company in the south as well, which now gives us the scope to do badge certification and release. As you license a pharmaceutical company, you are issued with a manufacturer's importation authorisation and there is a scope of activities you are licensed to do. Our business in the south is licensed to do batch certification and release. We are licensed to do that in Craigavon. We are part of the European Union today. We can release product into the European Union through that activity. Depending on these regulations and those arrangements and agreements you referred to, if they are seamless for us, then there should not be any interruption to our activity and to Almac's offering to our global customer base.

With the uncertainty that we have today, and Colin mentioned it, we had to make that decision in the immediate weeks following Brexit, because we need to start to put solutions in place here and that was the first step. It takes time to get that activity and that licensing done. We certainly hope that, in the fullness of time, there will be harmonisation of the regulations that affect pharmaceutical manufacturing and release. I certainly hope that. Without that certainty today, we need to take action to fill that gap from an Almac and from a client perspective. We do not know what they are thinking. We cannot influence their decision, because some of the clinical work we do and the formulation work we do are trials that can last three, four or five years, and then they feed into a commercial supply agreement on commercial terms, with a contractual relationship. You hope to have exclusivity in that arrangement. Decisions like the one we are facing today have influence in our customers' minds.

Q502 **Lady Hermon:** Do you mind if I ask about the facility? You have referred to it a number of times and in response to my colleague Alasdair well. That is about the Dundalk facility. Is it almost a replica in terms of size?

Graeme McBurney: No.

Q503 **Lady Hermon:** It is a safety net, but it is not a contingency plan. I think I need confirmation that, in fact, you are not intending to withdraw from Craigavon. There are too many people depending on you.

Colin Hayburn: No, we will not withdraw, not at all. We will fight, and we have always fought to protect the jobs and investment in Craigavon. There are no plans to stop.

Lady Hermon: It is very good to have that on the record.



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Colin Hayburn: To protect those jobs, we need to have a solution for the European Union, which is why we need facilities in Dundalk. If our customers ask us now to facilitate a study and do the work from the EU, we can facilitate that and that is what that is for.

Q504 **Lady Hermon:** That is very good. What you need on top of that, which is the main focus of our inquiry, is to achieve, however it is achieved, as frictionless a border as possible.

Colin Hayburn: If the border turns into something that is a further hindrance to our work, we will have to consider more operations being done in Dundalk. We will have to consider if it means it is too burdensome or unworkable and if we have to consider more operations. I do not envisage that we will ever be moving all our operations to Dundalk, but we will have to consider moving more if we cannot find a seamless, frictionless way of shipping product from Craigavon.

Q505 **Lady Hermon:** You have mentioned the number of shipments per year that might have to go through the Republic of Ireland. Could you describe how you export from Northern Ireland at the present time? How do your shipments move?

Colin Hayburn: We move some through Belfast and some through Dublin, more through Dublin because of the HMRC ruling recently, in the past year. Dublin is sometimes a viable route for us, for various reasons. Again, it is only an hour and a half from our facility, but the HMRC ruling meant that we could not reclaim VAT. I know I am repeating myself here, but we could not reclaim VAT if we brought it into the UK. We can reclaim it from the south. That is a massive benefit.

Lady Hermon: You have already established a pattern of activity. It will be the border that really matters—shipments crossing the border.

Colin Hayburn: Again, in that process, first of all we hope that HMRC changes its position, so that we will not have to do that. If it does not and we have to keep shipping product in and out of Dublin, again that hard border makes that more complex.

Q506 **Lady Hermon:** Can I just come to Stephen? Stephen, I wanted to know what you actually meant in response to a question. I took the quote down, so I will just quote it back to you: "People will take steps to avoid the customs checks and the paperwork". Now, I need you to tell me what it means by "people will take steps to avoid" them. You do not mean avoid them; you mean they will do some contingency planning.

Stephen Kelly: We have examples where firms currently based in Northern Ireland will close down their production facilities.

Q507 **Lady Hermon:** They are planning that already. Where will they move to?

Stephen Kelly: They will move either to the Republic of Ireland or they will move to the GB mainland. The reason for that, and it may sound weird—why GB?—is some of our food firms will ship out product at 6.00



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tonight and that needs to be guaranteed to be in markets at 6.30 tomorrow morning, in London and the South East. Those shipments will travel through Dublin port, because it is the quickest route, plain and simple. If you travel through Belfast, you need to travel down through Scotland and the UK. They travel through Dublin because that is the quickest route, there are more options and there are more services, and you are almost guaranteed that the product will actually make it to market here in London and the south-east of England by 6.30 in the morning.

If there is any requirement to produce paperwork, any risk in terms of any stops, checks or delays, either at the border or even exiting the EU through Dublin port, that puts in jeopardy that seamless, efficient supply chain that is already in existence. We are certainly aware of one particular major firm that is potentially looking at closing down their Northern Ireland facility and operating a facility in England instead. That is not lost to the UK as a whole, but it is certainly a loss to Northern Ireland. There are other firms that are clearly making the decision that, because of the nature of the business, and 75% of their trade may be in the Republic of Ireland, they are going to locate their next investment in the Republic of Ireland. That would potentially have an impact on the investment that they have in the north as well. We know that companies are making those plans and those plans will be put into action within the next 12 months, because investments will be required and planning.

Q508 Lady Hermon: Is that even before we formally leave the EU, because it is a two-year process and we have not triggered Article 50 yet?

Stephen Kelly: Yes, absolutely.

Lady Hermon: They will go beforehand.

Stephen Kelly: Factories are big and complex facilities to plan, to develop, to fund and to actually build, in many respects. Added to that is the supply chain and the support that goes around that, so firms are making those plans already. That is why we made the point that Northern Ireland and its agencies in the UK should also be out in the marketplace, in the Republic of Ireland and other parts of Europe, to those firms that see the UK as a marketplace, regardless of what happens with a trade deal or regardless of what happens with single market access for the UK post the Article 50 period. There is a sales opportunity there right now. Companies in Northern Ireland are making those decisions about potentially relocating either to guarantee to be within the EU or relocating to be in the GB mainland.

Lady Hermon: I do not want to be encouraging them to relocate out of Northern Ireland.

Stephen Kelly: Of course we do not, but we know that people are making those decisions and choices. That will also be the case for



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companies in France, Belgium, Republic of Ireland and elsewhere, which want to guarantee access into the UK market. We should be out pitching Northern Ireland to those places, because that opportunity still exists.

Specifically with the potential for Republic of Ireland firms travelling and moving north and having a presence in the north, in order for them to do that, we need to make sure that we have the most competitive economy possible. Right now, energy prices for those larger users are 20% more expensive north than they are south. Corporation tax rates are different north and south, and that is a good reason to press ahead with our corporation tax plans.

Lady Hermon: When the Assembly is up and going again.

Stephen Kelly: Exactly, yes. We want to make sure that the environment that those potential investors arrive into is an efficient, productive environment for them, so that they can make the best of their business and the best of their investment.

Lady Hermon: If the UK were to remain within the customs union, we would not have those problems.

Stephen Kelly: We would not have a lot of those problems. We understand that 177,000 lorries, 220,000 commuters and 1.8 million cars travel across over 300 border crossings every single week. Anything that adds 10 seconds' delay to that adds significantly to the uncertainty and the sustainability of firms in the north. For us, remaining in the customs union is an absolute critical factor on what the future economic prospects are for Northern Ireland.

Lady Hermon: I suggest a meeting with the Secretary of State for Northern Ireland would be very helpful.

Stephen Kelly: We have, Lady Hermon. You asked the question of colleagues here. We have facilitated some meetings for the Secretary of State with manufacturing firms in mid-Ulster in particular. There were two meetings late last year. We had a very good hearing. He is a very nice gentleman, as well. We know that those conversations are continuing. We are a little disappointed that what the Secretary communicated in those meetings is not fully reflected in the White Paper.

Q509 **Lady Hermon:** Was any of it reflected in the White Paper? What had you hoped to see in the White Paper?

Stephen Kelly: Certainly the strength of feeling around the needs for the customs union to remain, because it limits any prospect of having any friction at that border, is not fully articulated there. Certainly the intention of the UK Government is to look at potentially leaving the customs union, so there is still something to be played for there. We do not think those issues around that border are being fully understood, in terms of the thinking taking place around this negotiation and the times ahead.



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Q510 **Chair:** Can I just come back on the customs union? Correct me if I am wrong, but membership of the customs union would then restrict the right of this country to do trade deals beyond it. Is that not right?

Stephen Kelly: It potentially is.

Q511 **Chair:** Just last night I had dinner with an ambassador from one of the BRICS countries, who expressed great frustration that his country cannot do a trade deal with the EU. He is very enthusiastic about Brexit, because he sees an opportunity to do a trade deal with us. If membership of the customs union prevented that from happening, then we are giving up a great opportunity there, are we not?

Stephen Kelly: Chairman, we spent some time in China in October and November of this year. We have seen cities like Shenyang, which has a partnership with Belfast. Germany has been there since 1953, I understand. The industrial development investments that Germany has and the trading arrangements that Germany has in China are larger than pretty much the whole of the Northern Ireland manufacturing sector in just that one city, actually. We have not had anybody come to us and say, "We would love to replace the barriers in the way of free-flowing trade on the island of Ireland with a better deal with China", or South America, Australia or those other locations.

The reality for us is that we need to make sure that we look after our home ground as closely as possible. The value of manufacturing exports has grown in the last couple of years, but the number of manufacturing firms has declined, and that is despite having easy access into an export market in terms of the Republic of Ireland. When you asked the question about why that is the case, part of it is to do with competitiveness and we have not been competitive up until this year. The currency exchange has absolutely helped that, but it is actually really difficult to export. If it is really difficult to export from Derry to Donegal or from Newry to Dundalk, it is even more difficult to export to South America, China, Australia and elsewhere, although a lot of our firms do that and do that very successfully.

Q512 **Chair:** It is at the moment. The point I am making, though, is that remaining in the customs union might have some benefits, but it also causes restrictions. The real benefits of Brexit could be somewhat limited, in that our ability to do trade deals with some of the BRICS countries, for example, would be reduced. Alright, there might be some short-term benefits but, in a growing world where the growth markets are not in the European Union—they are beyond it—surely that would be a dangerous situation to take up, certainly in the medium to long term?

Stephen Kelly: Potentially, yes, it would, but the dangers that are staring our members directly in the face right now is a £478 charge every time they transfer anything across a border, and that is just the paperwork element of it, never mind any tariff elements. We have not even discussed the fact that, across the broader manufacturing sector,



the potential for tariffs is not as worrying as some people may believe. Certainly in some sectors, whether they are food, livestock and those areas, the tariffs are quite penal. In some of the pharma stuff, it is quite penal. In general manufacturing terms, like metals and plastics and stuff, it is quite a small percentage and not much of a concern. Much more of a concern is this administrative burden that comes alongside it, and the cost to administer that.

Q513 Nigel Mills: Mr Kelly, I think you just said that you thought the White Paper hinted that we might leave the customs union. It is a bit clearer than that, is it not? Does it not effectively say that we will seek a new customs agreement with the European Union?

Stephen Kelly: It says that, yes, but it does not say that we are definitely leaving the customs union as it stands, unlike all our statements about leaving the single market.

Q514 Nigel Mills: It does say, "A mutually beneficial new customs arrangement: after we have left the EU, we want to ensure that we can take advantage of the opportunity to negotiate our own preferential trade agreements around the world. We will not be bound by the EU's common external tariff." It carries on and it seems pretty clear that that is stronger than thinking about it.

Stephen Kelly: If the message from today is that the UK is definitely leaving the customs union, I have clarity on that and I am happy to give that clarity to those manufacturers at home that are concerned about this.

Q515 Nigel Mills: Would you favour a special deal for Northern Ireland, which kept Northern Ireland in the EU customs union but outside the UK customs union, in effect? Is that something that you think would be a bad idea?

Stephen Kelly: I know that not everyone in this House will accept their analysis of it, but one of the things that we heard on Friday at the all-island plenary was that the EU has the ability to be very creative around some things. You can understand why I am sure that not everyone in this House accepts that. Certainly the solution for Northern Ireland I think will require some particular arrangement, given our own unique circumstances in terms of the border, those 300 crossings and those 1.8 million cars that are travelling absolutely seamlessly and without friction right now, and the trade that comes with that. What that looks like will need to be developed by people at a higher pay grade than myself.

Certainly the expectation from our broad manufacturing base would be that whatever can be done should be done to ensure that there is no additional harm created particularly by that exit from the customs union. If that requires a special economic area or something more creative, like a free port status for Northern Ireland, or whatever the case may be, it



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would certainly be very much welcomed. I know that that is not in the gift of the EU, but is certainly in the gift of the UK Government.

Q516 Nigel Mills: I accept all that but, on the specific point of whether there is a choice for Northern Ireland of being in the EU customs union but not in the UK customs union or the UK customs area, is that something that you would be interested in, or would you think that that would actually put all the burdens and all the cost on intra-UK trade? That might be even worse than the cross-border ones.

Stephen Kelly: There is no ambition at all for any border, whether that is a land border north and south or whether that is a border across the Irish Sea. Both of those are equally damaging.

Q517 Mr Gregory Campbell: Do you mean an additional border?

Stephen Kelly: I think what was being suggested there is that it could be a choice between one and the other. Certainly any potential for a Brexit Britain with Northern Ireland outside of that is equally as damaging as potentially being outside the customs union, which is certainly not to be welcomed.

Q518 Nigel Mills: I am just trying to make sure I have understood the pharmaceutical issue, Mr Hayburn and Mr McBurney, just to make sure I understand what the precise issue is that you have. I think I understand that, for any new drug to be sold in the EU, it effectively has to be approved by the EU. In effect, it has to be signed off by a licensed operator. The person doing that sign-off currently has to be based in the EU. Is that right?

Colin Hayburn: It is, for drugs released for a clinical trial as well as released into the commercial market.

Q519 Nigel Mills: Forgive me if I am completely wrong, but Switzerland is quite big in the pharmaceutical industry. Can drugs licensed in Switzerland or approved in Switzerland be sold into the EU, or do they have to be rechecked somewhere across the border?

Colin Hayburn: They have negotiated a status. I just cannot recall it exactly.

Graeme McBurney: Switzerland has an MRA arrangement with the European Union. There is a term; it is an agreement on conformity assessment and acceptance, which means that a batch of product manufactured in Switzerland still needs to be QP-released into the European Union by a European QP in a European facility location. That QP can accept analytical data and manufacturing records from a Swiss facility, so that is one of the options here for any British manufacturer to supply product to the European Union in the future. It is one of those harmonised regulations. At this point in time, there is no certainty that I am aware of that there will be that seamless transition and an MRA, so that the Human Medicines Regulations between the UK and Europe can



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be applied on the stroke of midnight on whatever the date may be. That uncertainty drives most of our concerns and is how Almac is having to respond to the situation we have.

Q520 **Nigel Mills:** Even with the Swiss model, you would have to send stuff into the EU and have someone re-sign it off, in effect, so you could not just send it into the market.

Graeme McBurney: That is correct, yes. The Dundalk location and our company in the south of Ireland, which has approval today for badge certification and release, could work with an MRA arrangement and a QP-to-QP certification arrangement and technical agreement, so it basically accepts the data. The QP resides in the south of Ireland to do the physical release. A release is checking the registers and checking the manufacturing records against the marketing authorisation, and making a physical record in the approved register for approval at a subsequent period by a regulatory agency.

Nigel Mills: So it is a faff but not a disastrous faff in that situation.

Graeme McBurney: It is a challenge and it is another step in the chain for us, but we do not have certainty on an MRA today.

Q521 **Nigel Mills:** I am just trying to picture the position. I presume that we would not necessarily want to slavishly follow EU medicine licensing rules. We might have situations where we want to license a drug that they do not want to license, or similarly vice versa. Having complete harmonisation of at least the outcome would presumably not be easy to achieve, would it?

Colin Hayburn: I am not sure that we can fully answer that, but I am not sure why not. I am not sure why it should not be easily achieved. Some of that legislation is now in UK law. They are European directives, but in UK law, so I am not sure. The pharmaceutical industry is a global industry. I am not sure how bespoke we want ours to be in the UK, in relation to the release and approval of product, because pharmaceutical companies will release that product on a global basis. It would be highly unusual to release certain product into the UK and not into other European countries. There will be better qualified pharmaceuticals companies than us. We provide services to those companies. I cannot imagine why you would not seek harmonised equivalent legislation.

Q522 **Nigel Mills:** There are some drugs that are licensed in the US that are not licensed in Europe or vice versa.

Colin Hayburn: I am not sure that that is a legislative issue. That may be a governmental issue or another body's issue. I do not think it is a legislation issue.

Graeme McBurney: That is potentially a value issue or a NICE decision on the value of that drug. I am not speaking as a pharmaceutical representative, but speaking as a citizen: if there was a treatment



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developed within Europe for my condition, I would like to be able to get that, if I could.

Q523 **Nigel Mills:** If there is a treatment that Europe had said no to, you would like us to say yes, would you not? That is the trade-off.

Colin Hayburn: You still can. Even now you can.

Q524 **Nigel Mills:** As I say, this is all beyond my knowledge. In terms of tariffs and customs issues, have you looked to see what the tariff would be on moving your 84,000 shipments into the EU?

Colin Hayburn: We do not know what it is, you see. It is easy to say that, if we come out the customs union, we will have something else in place, but what will that be?

Q525 **Nigel Mills:** If we just went on to the EU's common external tariff now, do you know what that would be?

Colin Hayburn: No. We deal with World Trade Organization tariffs at times, when we ship outside the EU. There is something there, but it would just make us uncompetitive. There is no other nice way to say that. Our competitors will not have that issue; we will have that issue. It will make us uncompetitive.

Q526 **Nigel Mills:** I thought there were zero tariffs on lots of drugs these days.

Colin Hayburn: There is an exempt status for active pharmaceuticals, but not for placebos or comparator products. You have to pay full duty of 12.5% for a placebo. Active pharmaceuticals are exempt or zero-rated actually but, for a placebo or a comparator, which is a major part of your clinical package, you have to pay duty.

Q527 **Lady Hermon:** Could I just ask, out of curiosity, do not name them but where are your main competitors based? Are they based within the EU or are they in Switzerland?

Colin Hayburn: They are global companies. We would call ourselves a global company as well. They are global companies, but they have manufacturing and distribution capabilities in the EU.

Q528 **Lady Hermon:** Is that because of the benefits of being within the single market and the European customs union?

Colin Hayburn: Yes.

Stephen Kelly: I just have a comment on that last point. We know that manufacturing input cost inflation has risen by 20% in the last year, largely driven by a correction in terms of currency exchange. Manufacturers do everything that they can to try to reduce complexity and reduce cost. Anything that adds cost into that mix makes manufacturers uncompetitive and there is a return that makes them unsustainable. Tariffs, in terms of exporting goods, are one issue, but we also have the potential of items coming into the UK and into



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Northern Ireland with tariffs applied as well, which adds an additional burden in terms of some of those costs. Traditionally in manufacturing, raw materials is your number-one input cost, followed by staffing and, thirdly, energy, not always in that mix but largely in that mix. Anything that adds to those input costs, whether that is a tariff, a customs charge or whatever is really damaging. I am sure that would be something that is said by all manufacturers, not just our colleagues here today.

Chair: Thank you very much indeed for your evidence, gentlemen. It was very useful, thank you.