



HOUSE OF COMMONS

Northern Ireland Affairs Committee

Oral evidence: [Brexit and the Northern Ireland Protocol](#), HC 767.

Wednesday 11 November 2020

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Members present: Simon Hoare (Chair); Scott Benton; Mr Gregory Campbell; Stephen Farry; Mary Kelly Foy; Mr Robert Goodwill; Claire Hanna; Ian Paisley; Bob Stewart.

Questions 176 - 229

Witnesses

I: Colette Goldrick, Executive Director, Strategy and Partnerships, Association of the British Pharmaceutical Industry; Dr Richard Greville, Director, Distribution & Supply and ABPI Cymru Wales, Association of the British Pharmaceutical Industry.



Examination of witnesses

Witnesses: Colette Goldrick and Dr Richard Greville.

Q176 **Chair:** Good morning, colleagues, and good morning to our witnesses. Thank you for joining us this morning. I have two opening remarks before we turn to the substantive piece of business this morning. On behalf of the Committee, I would like to offer our congratulations to President-elect Biden on his election victory last week. I think we all recognise that he is very engaged with the issues of the island of Ireland and is no stranger to the opportunities and challenges of Northern Ireland. I know that we will look forward to working with the incoming American Administration on a number of issues of joint interest.

Secondly, today is the 11th day of the 11th month. If we are still in session as we approach 11 o'clock, I will suspend the session to allow for us to observe the traditional two minutes' silence.

We are joined this morning by Colette Goldrick and Dr Richard Greville. Could I ask both of you please, for the purposes of the record, to name yourselves and your organisations? Then, Colette, we will turn to you for some opening remarks, and then I shall throw you to the tender mercies of my Committee for a whole series of questions.

Colette Goldrick: Good morning, everybody. I am Colette Goldrick. I represent the Association of the British Pharmaceutical Industry, the ABPI.

Dr Greville: Good morning, everybody. I am Rick Greville. I am a supply chain director at the Association of the British Pharmaceutical Industry, the ABPI.

Chair: Colette, the floor is yours for about three or four minutes, if you will.

Colette Goldrick: I wanted to give a little context, before we get into the detailed discussion, about the association, the value of the industry to the UK and Northern Ireland, and some of the challenges we are facing. First, for any Committee members who are not familiar, the Association of the British Pharmaceutical Industry, the ABPI, exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies that invest in discovering those medicines and vaccines of the future.

I am responsible for our work in Northern Ireland, based here in Belfast, and my colleague, Rick, is our expert on the implications of EU exit on supply and distribution across the UK. We welcome the opportunity to provide evidence to the Committee's inquiry on Brexit and the Northern Ireland protocol. We understand that the Committee is particularly interested today in hearing about the impacts on the cost and availability of medicines in Northern Ireland, whether the agreement reached with the EU last week provides for long-term security of supplies, whether the



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agreement gives industry sufficient lead-in time to prepare for new arrangements, the likelihood of UK and EU regulatory regimes diverging in the future and industry preparedness for the end of transition itself.

Before we get into the detailed discussion of those points, to put the scale of the industry's value and the Northern Ireland supply challenge into context, across the UK, the pharmaceutical industry invests more than any other sector in R&D—£4.5 billion in 2018. The sector employs 63,000 people across the UK, with 24,000 of those dedicated to research and development. As a sector, it is six times more productive than average UK manufacturers, at £330,000 GVA per worker. It is a critical stabilising sector in a recession-hit economy and remains central to any long-term economic recovery that is centred on innovation, productivity and high-skilled quality jobs.

The EU remains the UK's closest and largest trading partner for pharmaceutical products. In 2019, 40% of the UK's pharmaceutical exports went to the EU, at a value of £9.4 billion, and 81% of the UK's pharmaceutical imports were from the EU. Turning closer to home for me in Northern Ireland, the pharmaceutical industry here employs 2,800 people and generates £310 million of GVA. It also indirectly supports almost 14,000 jobs, with a GVA of £910 million. The wider life sciences sector here in Northern Ireland employs over 5,000 people and indirectly supports over 18,000 high-quality jobs, delivering over £1.1 billion in GVA. We are a growing sector in Northern Ireland. That is also important to note. The latest figures show that the sector has grown by 14% since 2015, so it is a vital part of Northern Ireland's economic recovery strategy, too.

With regard to the scale of the logistical challenge of supplying the prescription medicines used by health and social care in Northern Ireland every day, manufacturers do not break down sales by UK Administration. The Northern Ireland hospital trusts do not publish expenditure on medicines as a separated cost. I cannot therefore give the Committee a precise figure for the total number of prescription medicines used here. To give you a sense of the scale, over 42 million prescribed items were dispensed in primary care alone in Northern Ireland in 2019. The vast majority of those, more than 80%, were supplied to Northern Ireland from Great Britain, with the Scottish ferry routes being the most usual means of transit.

To conclude these brief opening remarks, the ABPI has worked and continues to work intensively with the UK Government, our counterparts in Europe and across the island of Ireland to ensure that the implications for medicines regulation and supply posed by the end of transition are understood and mitigated. On behalf of the ABPI, I would like to pay tribute to the work of officials in the Northern Ireland Department of Health, the UK Department of Health and Social Care and the MHRA for working so collaboratively with us to make sure these challenges are understood and addressed by negotiators on both sides.



All industry efforts to plan for the end of transition are underpinned by a drive to ensure that patients across all parts of the UK can access the medicines they need. We are doing everything in our power to ensure that is the case, even in the midst of the second wave of the pandemic. The announcement on 5 November by the INISC of the 12-month phase-in period for regulation, batch testing, importation and falsified medicines directive requirements was very welcome, but it will now be important to ensure that does not represent a kicking of the can down the road and that the time is used productively by all sides. There is a lot more to be done in the next eight weeks and throughout 2021, so we look forward to taking your questions on the next steps and longer-term implications.

Q177 Chair: Conscious of that announcement last week, it would probably be useful if we keep in our minds during questions that we will be talking about the short term, which is slightly attenuated by that announcement, but could both of you couch your answers to the long term, when the end of that arrangement comes in? You spoke with great interest about the jobs and the numbers. Are you able to say anything at all about tie-ins and collaboration with the universities in Northern Ireland?

Colette Goldrick: That is a very important point. As an industry, we have extremely close ties with both of the Northern Ireland universities, which represent global beacons of excellence and attract great numbers of research collaborations from global member companies. We work very closely with them. We support all the efforts they are making to continue to attract that collaboration and make the results of it available to patients in Northern Ireland as well as to the sector in Northern Ireland itself. We pay tribute to both the universities for their incredibly dynamic efforts in this space.

Chair: That is helpful.

Q178 Ian Paisley: I wondered if Colette could give us a wee bit—just a couple of sentences—on the relationship the organisation has with NICE, how that affects the flow of drugs in and out of Northern Ireland, and the impact that no-name brand medicine has on the flow.

Colette Goldrick: In terms of the relationship with NICE, we work extremely closely with NICE. I am sure members will be aware that NICE is going through an extensive review of its methods and processes to ensure they are fit for the future. The ABPI is a key contributor to that work, so at a national level we work extremely closely with NICE. With regard to how Northern Ireland interacts with NICE, since 2013 Northern Ireland has interpreted the outcomes that NICE takes forward and made those decisions available to Northern Ireland patients within a very short space of time. There is a very close connection on a very longstanding basis.

I will pass the second part of your question to Rick, who is closer to that side of things.



Dr Greville: Sorry, I did not quite pick up the question. Was it a no-named brand?

Ian Paisley: Yes, where a medicine comes off being a specifically named brand. There is often a cheaper variant.

Chair: It is the off-patent stuff.

Dr Greville: Yes, so generic medicines. Generic medicines are extensively used throughout Northern Ireland in the same way they are throughout the UK. In terms of volume, they probably occupy about 80% of the medicines prescribed across the UK. Their trade representative body is the British Generic Manufacturers Association. That may be a group that you would wish to take evidence from in future.

Q179 **Chair:** With regards to the supply of medicines to Northern Ireland, what effect does the Northern Ireland protocol have on the ability to do that?

Dr Greville: We appreciated rather early on that the Northern Ireland protocol itself introduces the prospect of different regulatory factors controlling Northern Ireland, or the rules for medicines in Northern Ireland will be fundamentally different to the rules covering medicines in the rest of Great Britain. Before I expand on that, it is well worth reiterating the relevance of rules and regulations to the pharmaceutical industry. I am well informed that the pharmaceutical industry is probably one of the most highly regulated of industries—quite rightly as well, because of the safety and sensitivities involved.

Everything the pharmaceutical industry does is controlled and regulated by quite comprehensive regulations. That covers all aspects of medicines, from the early stage development, through clinical trials to the ongoing potential marketing of those successful medicines once they have been licensed. It also includes good distribution practice, so the supply and distribution of medicines is also highly regulated.

We understood, when the Northern Ireland protocol was introduced, that the prospect of introducing a different regulatory regime in Northern Ireland was going to be significant. The level of that significance was difficult to comprehend and understand initially, but in March of this year the European Commission published guidance that described its interpretation of how medicines would be regulated under the Northern Ireland protocol. From that time, we have been engaging with the UK Government to reach a joint interpretation of how the regulations will apply. I am glad to say that those discussions ended last week with a recognition that, to be fully prepared for those significant changes, there needs to be a phase-in period specifically for medicines.

We were reassured last week that the UK Government and the European Commission recognised the importance of a bit of extra time for the pharmaceutical industry to make suitable arrangements, alongside other partners in the distribution of medicines, such as wholesalers and pharmacies. This extra time is particularly helpful and useful for



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everybody to get their ducks in a row to ensure continuity of supply in Northern Ireland. The agreement itself is at the moment very much a headline announcement. We will continue to await more details as to what is precisely meant by a phase-in of the regulations, but we remain optimistic that it gives us appropriate and sufficient time to arrange our supply chains, because those supply chains will need to be changed significantly.

Q180 Chair: Have they given any indication as to how big this phasing-in window could be?

Dr Greville: It has been indicated that the window is for the whole of 2021. The suggestion is that the phase-in period will come to an end in December 2021.

Q181 Chair: This is just of general interest. When you made your case and presented the argument of hurdles and regulatory challenge and so on that your sector works within, and of how your sector would need to reflect and change practices to meet us leaving the European Union, was that met with surprise either in Whitehall or in Brussels? Was it readily understood, and therefore the phased-in 12 months was always in their back pocket, or were they saying, "Hell, we did not appreciate all of that. We had better create a phased-in window"?

Dr Greville: I wish I knew it was in their back pocket, if it was in their back pocket. We have had to fight long, hard and consistently to get this announcement of last week. Initially, there was not a full appreciation of the impact it would have on medicines by either the UK Government or the European Commission. Nevertheless, there was direct engagement by us with the UK Government and the regulator. Our sister European organisation, EFPIA, had similar conversations with the European Commission. Jointly, we have managed to provide the significant evidence that was required to demonstrate the need here for an extension or a phasing-in period for medicines in particular.

Q182 Chair: Were the UK to continue membership of the EMA, would that help at all in this challenge?

Dr Greville: There are various challenges to the direct involvement of the UK in the EMA, as you can imagine. The challenges that have been introduced are predominantly ones in relation to regulations. I see where you are getting, Chair. If we still worked under the European regulatory authority or agency, the problems would disappear. To some extent, they would do.

However, there is also the added complexity, I suppose, that the UK will become a third country compared to the rest of Europe. As such, being a third country in itself introduces some regulatory challenges. For example, medicines that enter Europe from a third country need to satisfy various importation requirements. That was one of the challenges we uncovered. As Colette mentioned, most of the medicines used in Northern Ireland currently are sourced from the GB market. The



wholesaler distribution system is predominantly based in GB and supplies Northern Ireland on a regular basis.

There is a wholesaler presence in Northern Ireland of course, but, in terms of warehousing, space and capacity, the Healthcare Distribution Association is well on record as identifying that only 20% of the various ranges of medicines that are prescribable in Northern Ireland are kept in Northern Ireland at any capacity. The remainder, the 80%, are shipped over to Northern Ireland on a daily or twice-daily basis, dependent on demand.

Q183 Chair: People who live in Northern Ireland will not really care by what route or regulatory regime their drugs arrive at their pharmacy, doctor's surgery or whatever. They will just want to know they are safe to take and are going to alleviate or remove the problem for which they have been prescribed. If one takes that as an overarching umbrella position—we are, at the end of the day, talking about public health and the health of the people of Northern Ireland—and notwithstanding the third-country relationship we will have with the EU, would membership of the EMA in any way help that flow of pharmaceuticals, safe for people to use, into Northern Ireland?

Dr Greville: I do not think there should be any suggestion that medicines will not be safe. The MHRA, as the UK regulator, has had a prominent role in the EMA for some years. There should not be any suggestion that the UK in the future will not be regulated to the high international standards that are required and needed for medicines.

Q184 Chair: I was not suggesting that there would be a sliding of safety standards. Forgive me; I might have phrased the point I was trying to get to clumsily. In terms of guaranteed supply between GB, NI and so on, notwithstanding being a third country, would membership of the EMA help with the logistics of getting drugs from A to B?

Dr Greville: If both GB and Northern Ireland were covered by the same regulator and under the same regulatory rules, yes, that would help.

Q185 Chair: To the best of your knowledge, could that be delivered as a third country?

Dr Greville: My understanding is that, no, it could not.

Q186 Claire Hanna: Thanks very much to the witnesses. That is quite reassuring and, I must confess, news to me about the lead-in time. Is it fair to say that you are confident that a long-term arrangement can be found, building on the specialised committee, for medicine supply into Northern Ireland?

Dr Greville: I think so. When we understood the changes that were happening we engaged with our members and took a straw poll, or a survey, as to how long they would take to make the appropriate changes in their supply chains, bearing in mind that it is not only their own



internal supply chains that they will have to engage in and change, but those of the wholesalers and distributors they use. The general feedback was that, to make those significant changes, they will need 12 months.

Just as long as the announcement last week can be taken as being entirely correct, that flexibility of an additional 12 months, for the whole of 2021, should provide sufficient time to ensure all stakeholders can make the changes that will be required during that time.

Q187 Claire Hanna: Do you now foresee any scenario like we have with the supermarkets, which are warning about certain product lines? Could we have a scenario where certain medicines, either existing or in development, would not be available in Northern Ireland or that there would be additional barriers to accessing them?

Dr Greville: Again, I do not envisage that happening. For the medicines that already have marketing authorisations, into the future, those authorisations will be either European-based or UK-based. They will be issued by either the EMA or the MHRA. I do not think there is any suggestion that some medicines will not be transferred from their current marketing arrangements to future marketing arrangements. For new medicines that are introduced to the market or become available for prescribing well into the future, again, the marketing authorisation holders will decide as to which marketing authorisation route they follow. It is envisaged that they will continue.

Of course, all marketing authorisations are discontinued on an ongoing basis, so medicines become available and are then withdrawn from the market. There is an ongoing process by which companies can withdraw from a market. That includes six months' notice to the appropriate authorities. In most cases, that is of the authority with responsibility here, which is the Department of Health and Social Care in Westminster, because it is a reserved power.

Q188 Claire Hanna: You mentioned that most of the supply here is hubbed in GB, and you referred to the falsified medicine directive, which obviously will not apply in GB. Do you sense any appetite for medicine producers in GB to diverge from standards to the extent that it would not be profitable to ship to Northern Ireland, or do they have sufficient markets elsewhere in the EU that it will be profitable and sensible for them to match and peg to the EU standards?

Dr Greville: You introduce an interesting concept, that of the falsified medicines directive. I do not know how well the Committee understands the falsified medicines directive. Perhaps, if I describe it for a couple of minutes, that might be helpful.

Q189 Chair: Could you give us the bullet-pointed version?

Dr Greville: I will do my best. The safety features aspect of the falsified medicines directive means that each individual pack of medicine is now uniquely identified by means of various codes and a 2D matrix, which



allows the scanning for those codes to be picked up by pharmacy, either in the hospital or in primary care. That means that each individual pack of medicines is uniquely identified, which is helpful in ensuring that counterfeits would have a further obstacle before entering any market surreptitiously. That is the intention of the falsified medicines directive—to create an additional barrier to counterfeits entering any particular market.

As you mentioned, Northern Ireland, under the Northern Ireland protocol, will retain that facility. We assume that the packs of medicines supplied to Northern Ireland sometime in the future, not necessarily during 2021 but certainly in 2022 and onwards, will be expected to have this identifier on them. The challenge is that GB packs of medicines, from where Northern Ireland supplies are currently sourced, will not have the obligation of having this unique identifier on them.

In fact, the European Commission insists that, even if those packs of medicines hold a unique identifier, the data cannot be held centrally, so there is not a means of verifying that pack of medicine in GB, or, if that pack of medicine was supplied to Northern Ireland, there would not be a means of verifying that pack of medicine in Northern Ireland. That is where some of the trouble begins.

If a pharmacy cannot verify a pack of medicine in Northern Ireland as being authentic because of its unique identifier, the pharmacist will be expected to quarantine that pack and not pass it on to the patient. Into the future, Northern Ireland will have to be supplied with packs of medicines that are compliant with the FMD. I think, Claire, that is what you were alluding to: are there packs of medicines that could be supplied to Northern Ireland, if not from GB, from other parts of Europe? That is part of the work that individual companies will have to work through next year.

Q190 Claire Hanna: I will not labour it, but do we sense that manufacturers in Britain want to go in a different direction, or is it in their economic interest? Is a substantial enough part of their market in the rest of the EU? You said there is not really a clear picture on that. You need to see what the next 12 months bring.

Dr Greville: There is not a clear picture on that, but we have to recognise that most medicines are marketed throughout Europe. Obviously there will be an ongoing need for medicine in the rest of Europe to have a falsified medicines directive unique identifier on it, so there is a case of identifying which medicines are best aligned to what is required in Northern Ireland, to make sure that is used as a source of medicines for Northern Ireland.

Q191 Chair: You said “would not” or “could not”. With regards to the data, is this just a requirement for a review of regulation to meet the new political circumstance, or is there some insurmountable regulatory barrier that means that these codes could not be verified or would not be



verifiable?

Dr Greville: Yes, there is a barrier at the moment and the barrier is a regulatory barrier. For all medicines that are exported from Europe, the Commission expects and requires that this unique identifier, if they hold it, is inactivated or decommissioned.

Q192 **Chair:** What is the reason for that?

Dr Greville: They see this verification system they have introduced as being an EU-only system that should not be used outside of the EU.

Q193 **Chair:** That strikes me as a peculiarly bonkers position for the EU to take, given the vast number of EU citizens who reside now within the United Kingdom and will continue to do so—and/or visit—and who will be picking up prescribed medicines for all sorts of conditions. One would think that the EU would think it had a duty of care to the public health of EU citizens, irrespective of where they were.

Dr Greville: We were very hopeful that, during negotiations on the future relationship with Europe, as part of the comprehensive trade deal that we have asked for from day one, there could be some arrangements like that made. I am sorry to say, with a small number of weeks left now before the end of the year, we cannot hold out promise for that, but I have some sympathies with your view, Chair.

Q194 **Chair:** From your conversations with the UK Government, do they have sympathy with it too?

Dr Greville: The UK Government have had to respond to the position taken up by the European Commission. The UK Government, as part of the legislation they have laid, have laid a statutory instrument that amends the medicines regulation that will come into play as and when we finally leave the EU. That confirms that the legislation relating to the falsified medicines directive in GB will actually be revoked.

Chair: That is an answer, but it is not a particularly good answer in terms of public health outcomes. I do not blame you for that, but let us hope that, during what remains of this year and during 2021, this rather pettifogging point, as important as it is, can be rectified.

Q195 **Mary Kelly Foy:** Good morning, Colette and Richard. I have a few questions here. First, I would like to ask how the Northern Ireland protocol, or Brexit more widely, might change the pharmaceutical sector's approach to where it sources medicine for the Northern Ireland market. Will any changes in approach affect the availability or cost of medicines?

Dr Greville: As I mentioned earlier, the source of medicines into Northern Ireland may need to change into the future. The ability to source medicines from the GB market may well be removed because those medicines may not have a falsified medicines directive unique identifier on the packs of medicines, or that unique identifier may be inactivated. That pack would either have to be relabelled before it was



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issued to Northern Ireland or, as you mention, that medicine could be sourced from other parts of Europe and either transported directly to Northern Ireland, using GB as a land bridge under what is termed the common transit convention, which the Committee may have dealt with previously, or supplies could be made directly to Northern Ireland without leaving the EU. That would be either directly to Northern Ireland or via the Republic.

You asked the question about the cost of medicines. It is probably useful at this time to remind the Committee of, or introduce the Committee to, the voluntary pricing and access scheme, which applies to branded medicines across the UK. The voluntary scheme at the moment ensures that there is a cap on expenditure on branded medicines right across Europe. That voluntary scheme in itself does not allow or permit any ad hoc price rises in the cost of branded medicines.

In terms of the prices of branded medicines, it is unlikely that those costs will change. Even if they did, there is this capping mechanism, which ensures that the Department, on behalf of the rest of the UK, gets a VPAS payment on a quarterly basis, which makes up for any difference or any expenditure over and above that cap. It is unlikely that there will be any changes in the price of branded medicines, although you have probably identified that the costs associated with distribution and supply may indeed change and may have increased.

Q196 Mary Kelly Foy: Colette, is there a danger that some of these medicines will fall under the definition of at-risk goods and then be subject to EU tariffs on entering Northern Ireland?

Colette Goldrick: Apologies for pushing this back to Rick. Rick, you are probably best placed to answer that question because you are closer to that. Before I pass the question back and for the record, I think Rick was describing the impact of the voluntary pricing and access scheme, which operates across the UK, not across Europe. That was just a little misspeak.

Dr Greville: Did I mention the EU? I meant the UK. Sorry, no, it is a UK-only scheme. Thanks, Colette, for picking that up. In terms of being at risk of movement to the Republic, it is unlikely. In fact, the falsified medicines directive introduces a useful monitor of the movement of medicines. Once they have this unique identifier, medicines will create an audit trail of movement across Europe. We do not envisage that there will be an issue of tariffs. Supplementing that, medicines under the WTO scheme tend to be excluded from tariffs in any case. It is only active pharmaceutical ingredients as a base product that sometimes attract tariffs, so we do not expect tariffs to be an issue for a couple of reasons.

Q197 Mary Kelly Foy: Finally, to push a little further, it is quite clear that the end of the transition period is going to be extremely disruptive, especially in the middle of winter, when we are battling with this pandemic. Could you briefly outline what the implications for the importation of medicines



into Northern Ireland will be in a no-deal scenario?

Dr Greville: There probably is not any great difference between a no-deal scenario and a deal that is likely to be achievable in the remaining few weeks. Covid and winter pressures certainly increase the pressures on supplies of medicines. As long as we get this agreement for a phase-in period during 2021, we do not see that as being of particular relevance specifically for Northern Ireland. We hope that the current distribution system will still be allowed to proceed, at least in the short term.

Mary Kelly Foy: That is reassuring.

Q198 **Mr Campbell:** Welcome to the two witnesses. I have an overarching question, with maybe two or three questions flowing from it. You said that the bulk of medicines, supplies and prescriptions for Northern Ireland come from the GB marketplace. Has that changed in the past 10, 15 or 20 years, or remained largely static?

Dr Greville: That has remained largely static to my knowledge.

Colette Goldrick: I would confirm that. That is a fairly constant picture.

Q199 **Mr Campbell:** Is that about the order of 80%?

Colette Goldrick: It is about the order of 80%, yes.

Dr Greville: It is about the order of 80%.

Q200 **Mr Campbell:** During all that time, and I presume previously as well, has any evidence emerged of any of the product coming from GB into Northern Ireland ending up for distribution, sale, use or misuse in the Irish Republic?

Dr Greville: It has. The single market has allowed the movement of medicines, alongside other goods, from Northern Ireland to the Republic, and from GB and within the EU, fairly consistently. There is a complexity to the movement of medicines, as there is a complexity to the movement of most goods. Within the single market, there was an ongoing flow of goods. In the future, with the UK, and specifically GB, being considered to be outside of that single market, you would perhaps expect less movement of medicines from GB to the rest of Europe, including Ireland.

Q201 **Mr Campbell:** Given the land border being open, and that it is going to continue to be open, I can understand why there would have been in the past an element of the product appearing in the Irish Republic. Did that present a problem? Did anyone identify that as being problematic? Was that anything to do with the quality of the product, or was it just something we knew would happen? The single market allowed for it and it occurred.

Dr Greville: Absolutely, yes. There is certainly no impact in terms of quality. It is really important to stress that, and there is no issue in terms of patient safety or anything. However, the ability for goods to move across borders is an important one in many ways and certainly that was



the case in the single market. It will remain the case between Northern Ireland and the Republic under the Northern Ireland protocol.

Q202 **Mr Campbell:** There was no danger to product in the past and therefore, one would assume, no danger to product in the future, or to people's health either.

Dr Greville: Yes, correct.

Q203 **Stephen Farry:** Good morning to our witnesses. I want to pick up on some of the more granular detail around the falsified medicines directive to begin with. You have largely answered a fair degree of this, but in terms of the potential rerouting of supplies through, in particular, the Republic of Ireland, for example, is regulation entirely at a European level, or are there some domestic issues as well? I have heard from some people that there may be some regulatory or licensing issues in the Republic of Ireland around certain drugs that may mean that rerouting medicines is not entirely straightforward. Is that your understanding too, or is the rerouting from another EU country entirely simple?

Dr Greville: The falsified medicines directive is covered by the directive itself and is covered by a delegated regulation. That delegated regulation covers all the member states to which it applies, so I am not entirely sure as to any challenges there. There are various aspects of regulation that are European, and other aspects are under the control of the national regulator. In Ireland, the HPRA is the equivalent of the UK's MHRA, as you probably know. It has national flexibilities in certain aspects of the regulation of medicines, in particular medicines that are termed "specials" in the UK context, but are referenced as "exempt medicines" in the Republic. In those circumstances, the regulations are not covered by European-wide regulations. They are covered more by local national regulations and then are privy more to national interpretation. Does that help?

Q204 **Stephen Farry:** It does. To drill down a little, are you happy that that route is going to work okay, or are there issues, for example, that some of us would need to raise with the Irish Government to ensure there is an entirely free flow? Is it entirely plain sailing as far as you can see, on a practical basis?

Dr Greville: We do not see any obstacles to the flow that we are aware of currently. However, companies tend not to use that route at the moment, as we have discussed, so this is going to be a potential new route for some medicines and for some companies. It is certainly not an exclusive route and certainly is not a route that will be used by all companies, or, in fact, by any individual company for its whole portfolio. The reality of the situation is that some medicines are authorised or licensed in the Republic and some medicines are differently licensed in Northern Ireland. In that case, it would not be appropriate to move those medicines across the border. Where the licences or the marketing



authorisations align, there should be facility to move those medicines from one place to the other within the island of Ireland, yes.

Q205 Stephen Farry: Turning to the GB route, it is a terrible term for Northern Ireland, for obvious reasons, but, essentially, the medicines coming from continental Europe into GB for distribution are de facto decommissioned, in terms of the FMD. Is there scope for something like a cabotage system being put in place, where a package that is separated for the Northern Ireland market is under severe lock and key, and can still retain its classification under the FMD? Is it the situation that, once they enter GB, they are decommissioned entirely?

Dr Greville: The cabotage approach is one that probably describes the common transit convention. The common transit convention allows medicines to start off from Europe, hop, skip and jump through Great Britain, as you say, under various bonding arrangements and secure arrangements, and then land in Northern Ireland. In that instance, it would be fine for the falsified medicines directive unique identifier not to be deactivated on export from Europe. When it lands in Northern Ireland, it would be active and available to be scanned and verified directly in Northern Ireland. The cabotage bit is the movement of goods under bond or under security through Great Britain. As long as it moves through Great Britain faster than 90 days, I think that would apply.

Q206 Stephen Farry: That is good to know. Finally, you said earlier on that, at this stage, the emerging work through the specialised committee is still at a very high level. Do you have any concerns or are there any risks there as to what that may contain when we see the detail? Is that going to be entirely to your satisfaction, or is there some risk still?

Dr Greville: I would love to be able to tell you that there are not any risks attached, but we do not know. We honestly have to await the details. We have our fingers crossed that the details confirm the announcement that was made last week and that we have a very phased-in approach to the implementation of the various regulations. That phase-in is absolutely critical. As you can imagine, the detail of that phasing in will inevitably be important as well because of the high reliance of the pharmaceutical industry on following rules and regulations. If we were more slipshod in our approach to rules and regulations, you would have that flexibility, but the pharmaceutical industry cannot be slipshod in rules and regulations, so we will abide by them fully.

Q207 Stephen Farry: The final point to make is that we are very conscious that there is a vaccine at a very advanced stage, which may be made in Belgium. That then goes to the UK, and Northern Ireland gets its share. Any risks in that regard would be of concern to us in Northern Ireland, come the early spring.

Dr Greville: Yes, absolutely, and I am sure there will be appropriate engagement with the UK Government, who have, I am led to believe, taken responsibility for purchasing those medicines on behalf of the UK.



It is really important to get through the detail and ensure that there is onward supply to Northern Ireland.

Q208 Chair: Can I reflect broadly on what I think the Committee has been hearing from our witnesses this morning? I will bullet-point summarise it, because I think this will be important for those who live in Northern Ireland, who have plenty of things to worry about, with Covid and everything else at the moment. 31 December approaches. With or without a deal, transportation, prescribing and access to drugs will continue uninterrupted during next year while work, which it is agreed needs to be done in order to have a permanent regulatory arrangement put in place, will be done. If you are sitting in Northern Ireland today, worrying about access to medicine A, B or C on 1 January, moving forward next year, you can strike that off your worry list at the moment. Is that a fair assessment as to where we are?

Colette Goldrick: That is a really important point to reinforce in our evidence this morning and for patients who may be aware of this session. That is absolutely the case. The announcement last week, to the best of our understanding, means exactly what you have just said, that no patient in Northern Ireland need worry on 1 January, whatever happens, that they will not be able to access the medicines they are currently being prescribed.

Q209 Chair: Is there anything we can do as a Committee to hold the toes of those whose toes need to be held to the fire, to dot the Is and cross the Ts and to formalise this—and I am going to use this word—phased window, in order to allow that work to be done? Is there anybody that you would say it would be really helpful for the Committee to write to? Is it Michael Gove? Is it Matt Hancock? Is it Ms Foster? Who is it?

Dr Greville: It would be very useful, if we find out that this phase-in announcement does not work as you described, for us to get back in contact with the Committee and highlight what our concerns would be. It would be very useful for us to have that facility.

Q210 Chair: Do you know at this juncture which UK Minister has been charged with delivering it?

Dr Greville: The announcement was issued by the Cabinet Office. The announcement itself came from the Cabinet Office.

Q211 Chair: I am going to suggest to colleagues that we communicate our support for this window to Michael Gove, CDL, and hope that it is all put in place. It is clear that he is alert to the seriousness and necessity of this, but I do not think a communication from us would be unhelpful.

Dr Greville: That would be very helpful. Thank you, Chair.

Chair: No colleague has thrown a rotten banana at me, actually or virtually, so I will take it as support for that. Here is somebody who never throws a rotten banana, but a good curveball from time to time, Mr



Robert Goodwill.

Q212 **Mr Goodwill:** What we have just heard is very reassuring for people in Northern Ireland, regarding the phase-in period. However, it may be, in some situations, that we are just kicking the can down the road until 1 January 2022. Will medicines sold in both GB and Northern Ireland need separate authorisation and batch tests for each market? I understand that the unique identifier will need to be placed on products put on the market in Northern Ireland. Was I correct in hearing that, if that same product, with the unique identifier for EU purposes, was put on the market in GB, that would not be permissible? Could we just put the unique identifier on everything, whether it is sold in Northern Ireland or elsewhere?

Dr Greville: All marketing authorisations in the future in GB will have to be ones issued by the MHRA. There is a process by which the current marketing authorisations that have been issued by the EMA over the past few years are converted into GB licences, so that is the case.

For medicines in Northern Ireland, believe it or not, we are led to believe that there will be five options or five types of marketing authorisations that exist. Three of them will be as currently, so they will be the three marketing authorisations currently issued directly or via the EMA. Over and above that, the MHRA will also be able to issue a specific marketing authorisation for Northern Ireland only. Also, it will be able to issue marketing authorisations for the whole of the UK, which would include Northern Ireland and GB.

Perhaps that begins to explain some of the complexity here and why I mentioned earlier that companies, when they consider their distribution and supply chain for medicines, will have to consider each of those individually. They will not only be dependent on the marketing authorisations, but each medicine will also have to be considered in terms of importation requirements, as well as the falsified medicines directive.

Q213 **Mr Goodwill:** Will this create any delay or obstacle in supplying medicines to Northern Ireland compared to GB, or even in terms of GB manufacturers supplying the rest of the world or the European Union?

Dr Greville: It partially explains why we need next year as a phase-in period so that companies can make the appropriate arrangements not only in terms of labelling and packaging of medicines intended for Northern Ireland, but also with their distribution chain. Take wholesalers, for example. It may be that in future, companies and manufacturers would need to make contractual arrangements with wholesalers, and not necessarily the ones that they currently use in GB. They may choose to distribute via, for example, the Republic or, using the earlier example, perhaps from other parts of Europe that hop, skip and jump through GB into Northern Ireland.

Q214 **Mr Goodwill:** The relationship between the EMA and the MHRA could not be described as mutual recognition in any way.



Dr Greville: It is not mutual recognition at the moment. One of our asks is that, under a negotiation of a trade deal, there is a mutual recognition agreement, but that is not being offered at the moment, or certainly has not been accepted by both sides, although we are very well aware that the UK Government have been strongly advocating for a mutual recognition agreement to be established.

Q215 **Mr Goodwill:** Following on from that, I note that one of the lines in the documentation is that the UK may not act as a “leading authority” for assessments, examinations or authorisations. Is that a signpost to the fact that the UK authorisation will always be playing second fiddle to what the EMA might be deciding or ruling?

Dr Greville: Yes. The way that the Northern Ireland protocol has been written confirms that the EU marketing authorisation will take precedence for medicines in Northern Ireland. If, for example, a medicine holds both a GB authorisation and a European authorisation, the European authorisation is the one that will apply to the medicine that is available and dispensable in Northern Ireland.

Q216 **Mr Goodwill:** We have been talking a lot about east-west trade and, as you said, 80% of the trade is just in time from GB to Northern Ireland. Are we likely to see more business going north-south from the EU into Northern Ireland because of the simplicity of having unique identifiers and authorisation with the EMA? Is it likely that GB could lose out in terms of trade into Northern Ireland because of this?

Dr Greville: The level of trade north-south at the moment is very little in terms of medicines, but, into the future, it may well be that that route is deemed to be a more suitable one or a more efficient one than currently. It is really difficult to know as yet what sort of percentage we are talking about and the north-south route may remain seldom used. Nevertheless, it is probably becoming more attractive than it has been historically. Because of the lack of usage historically, the systems are not really in place for that north-south movement, so it would need to have a new distribution chain established. It would require inevitable significant investment and resourcing to do that. Potentially, yes, but, in reality, we will have to wait and see.

Q217 **Mr Goodwill:** Could I ask you specifically about cancer drugs and, in particular, cancer drugs that may be part of the cancer drugs fund or given limited authorisation? You talked about specials or exempt products. Currently, that allows faster access to the most promising cancer treatments. Since 12 September 2018, the Department of Health in Northern Ireland has allowed that same access to drugs that have been given that type of authorisation from NICE. Is that situation likely to change in Northern Ireland? Some of these drugs, particularly those for patients with terminal illnesses, are experimental with very temporary authorisations. Would that mean that patients in Northern Ireland would not have access to those more experimental drugs or to new drugs in development?



Dr Greville: The new drugs in development would be covered by this specials arrangement. The movement of those and the regulations applying to those are fully within the control of the MHRA, so I would be reassured that that would not be impacted in any other way. It is an area that is well worth following and any challenges that happen to the movement of those oncology medicines would need to be monitored, of course.

Q218 **Mr Goodwill:** Finally, would that also apply to vaccines? A number of vaccines for Covid are being fast-tracked and are maybe not going through all the authorisations. Various testing is being done in parallel rather than sequentially. The same would apply, in that if a vaccine is available in GB it would also be available in Northern Ireland, even if that vaccine has not been authorised or allowed in the European Union.

Dr Greville: Yes. In that case, if that medicine was covered by a marketing authorisation that was UK-wide, obviously that would then apply in Northern Ireland as well as GB.

Mr Goodwill: That is very reassuring.

Q219 **Mr Campbell:** Dr Greville, did the EU or anyone you spoke to in the Commission give a rationale as to why they would object, either strongly or otherwise, to the mutual recognition concept?

Dr Greville: The mutual recognition agreement is really important from a pharmaceutical industry perspective because it would potentially minimise any duplication and maintain efficiency in the supply chain not only of the manufacturers, but of the inspectors. Inspectors in GB would not have to inspect premises on manufacturing sites in other parts of Europe, for example, so there are significant benefits to the mutual recognition agreement.

I have not been fortunate enough to have any direct conversations with the Commission, so I cannot give you a direct answer other than that we strongly believe that the UK Government have been advocating a mutual recognition agreement to be signed off for some time. We are led to believe that the European Commission, for whatever reason, does not hold that view currently. We are very hopeful that, before the end of the year, we will get a mutual recognition agreement.

Q220 **Chair:** Mr Goodwill has mentioned cancer drugs. Many on the Committee will be aware of very strong campaigning in Northern Ireland vis-à-vis access to medical cannabis for epilepsy and other conditions. There does seem to be some hiatus in the prescribing. Does this situation have any impact on that, beneficial or otherwise?

Dr Greville: No, not as I understand it. My understanding is that there are licences available for medicinal cannabis, but perhaps the prescribing does not support the licences that are available. I assume that is due to reasons not to do with the licence or not related at all to the supply of those medicines to Northern Ireland. It is a separate issue.



Q221 **Scott Benton:** Good morning to both witnesses. Although the UK Government have not yet indicated whether they intend to make any specific changes to the UK's regulatory regime, the Health Secretary has alluded to this as a distinct possibility in the future. How likely do you think it is that either the UK or the EU will change medicine regulation and it will be, in effect, different in either territory? What potential challenges do you think arise for Northern Ireland?

Dr Greville: We have identified changes or differences in the regulations from day one. That is predominantly due to the falsified medicines directive and the labelling requirements on medicines. That divergence has happened, or will happen, from day one. That is why it is really important to have this phase-in period to mitigate that to some level.

In future, I suppose it is inevitable that there will be divergence in regulations as time progresses. We are not aware of any emerging differences other than the ones that normally pertain to regulators, and I mean various variations in patient information leaflets and various labelling requirements on packs of medicines. Inevitably, they happen all the time. If they happen in the EU and they do not happen in terms of the GB regulations, obviously there will be additional diversions there.

There are also conversations about diversions in process, but it is really important that the regulation of medicines is generally covered by international standards. I do not think that there is any real suggestion that those international standards are dropped or changed on either side. There may be changes in process, speed of marketing authorisations and suchlike. In that case, I suppose Northern Ireland could be considered to be in the best of two worlds potentially, qualifying for both EU and GB regulation and authorisations.

Q222 **Scott Benton:** Are there any areas in which the industry would potentially like the UK Government to take a different approach to the regulatory regime and alignment? Do you see any benefits, potentially, of the UK Government doing so?

Dr Greville: Reflecting on the experiences of recent months, Covid has certainly brought lots of challenges to everybody's lives. Inevitably, Covid has also demonstrated what can be done in the development of medicines and how the authorisation of medicines can be fast-tracked. We would hope that some of the learnings that have been picked up from adversity through Covid could be continued into the future, but, again, without the compromise of international standards and patient safety. Just to reiterate, it is great to have shortcuts, but, inevitably, those shortcuts should not compromise patient safety or international standards.

Q223 **Chair:** My take is that the Government's approach of having up to a 12-month window avoids any need for the stockpiling of medicines, which is, of itself, a good thing. What is your view? Has this been communicated well enough to doctors, dispensing pharmacies and the



pharmaceutical and life sciences sector?

Dr Greville: Stockpiling in itself is almost a PhD thesis, but there are stockpiling asks that the UK Government have made of industry to overcome any disruptions in the channel crossings, and therefore supply of medicines to the UK in general. There is a stockpile or a buffer-stock ask there by which the Government have asked the industry to have at least six weeks' stock on UK soil at the end of this year. That is one stockpiling aspect.

Again, we await the details of the phase-in period and the devil, as always, is in the details. If it works as we hope and as written, there will not be a need for stockpiling in Northern Ireland or for Northern Ireland. However, there is also the likelihood that the companies, in their risk assessment, may well consider that it might be helpful for them to be holding some FMD-compliant packs somewhere in the UK, if not in Northern Ireland itself. There may well be some individual company contingency arrangements that consider and look at stockpiling of medicine specifically for Northern Ireland, even for the phase-in period.

Q224 **Chair:** Many of us, as constituency MPs, will have heard during the first lockdown of additional pressure put on pharmacies across our constituencies from patients seeking three or four-month supplies of whatever drug they were taking, because of the panic that there may be a problem with the transport logistics, production, opening hours, lockdown and so on. I take on board the point that the corporates are likely to have insulated themselves from any cross-channel disruption, but, for the ordinary man and woman in the street, there is no need for them, at the start of December, to be saying to their doctor or to their pharmacist, "Can I have a prescription, please, for drug X, Y or Z for three months rather than my usual four weeks?" Is that correct?

Dr Greville: That is very much correct. That is a really important message that would be very useful to reiterate in Northern Ireland. It is really important. Throughout today, we have considered the supply issues and we have not considered the demand issues, but, obviously, the balance is needed between supply and demand. We are aware that during early Covid, for example, such increases in local demand by patients did compromise or pressurise the supply resilience of medicines. We managed to work our way through it, but it is really important. I will stop there because I know Colette wants to input as well.

Chair: We could effectively pray in aid the cri de coeur of Corporal Jones.

Dr Greville: Don't panic.

Colette Goldrick: We worked very closely during the first phase of the pandemic with officials in Northern Ireland at both the departmental level and the medicines management level to make sure that patients did not panic. At first, there was an initial surge in requests for longer-term prescriptions, but we are pleased to say that that very quickly worked through and there were no significant issues arising from patients simply



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being concerned about getting their medicines during the pandemic. We plan to continue exactly that dialogue as we come up to the end of the year to ensure that those same messages go out and, again, that those requests are not leading to unwarranted supply shortages.

Q225 Chair: I have two final questions. I asked you whether you thought it would be helpful to send a note to the Cabinet Office. You agreed and the Committee concurred. If we revert to the point I was making about the duty of care that one would hope the EU has for EU citizens living in or travelling to the UK post 1 January, deal or not, it must have an obligation to try to keep its people safe. Would it be of any assistance if this Committee were to write to Monsieur Barnier or to anybody else to make that point with regards to an element of public health realpolitik being delivered in this debate for the next couple of months?

Dr Greville: The announcement made by the Cabinet Office last week was an announcement of a joint agreement. It would be particularly helpful, Chair, if you wrote not only to the UK Government side but also to the European Commission side encouraging a phase-in for 2021. That would be great.

Q226 Chair: Again, I see no rotten bananas being hurled at me from colleagues so I will take that as acceptance of the proposition. My final question is about rogue drugs. If some dodgy factory somewhere is producing counterfeit drugs or something or other, what risk is there of the UK drugs market becoming an opportunity for those people to exploit our market in the absence of the seamless, robust, reliable regulatory and transport logistics regimes that you discussed earlier in evidence?

Dr Greville: The GB component will certainly miss out by not having access to the falsified medicines directive and the obstacles to counterfeits that that provides. However, it is not the case that that will not be replaced by another system into the future. As part of the statutory instrument I mentioned earlier that is currently going to be enacted as we leave the EU, there is a commitment that the UK Government will revisit a means of authentication and verification for medicines as they apply in GB. It is just unlikely to be able to be the falsified medicines directive system, because that is deemed to be exclusively for European use.

Q227 Chair: Whatever it is and whatever we call it, it needs to come on stream seamlessly with the ending of the current regime in order not to create that vacuum.

Dr Greville: Indeed, a vacuum is never good. The feasibility of it coming on board within a year is something that I am sure the UK Government themselves will have to consider.

Q228 Claire Hanna: I wanted to come back in on the same issue, because I do not have it clear in my head. I suspect that is because the outcome is not completely clear. Just to try to get clarity, in terms of this EU-specific identifier issue, you think that Northern Ireland will need to find other



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suppliers and the majority of them are more likely, after this phasing-in period, not to come through Britain, but to come through the Republic, for example.

Dr Greville: They will not definitely come from the Republic; some of them could come from other parts of Europe. It is really important to recognise that medicines that land in Great Britain and are placed on the market of Great Britain will be expected to have their unique identifier deactivated. The option remains for that identifier to be reactivated before it gets transported to Northern Ireland. However, that is quite a significant extra step that would be required that does not have the infrastructure currently. That one option remains.

However, it is perhaps more likely that, in future, Northern Ireland medicines will be shipped directly from Europe into Northern Ireland, avoiding Great Britain as a marketplace. Medicines will either move from Europe into Northern Ireland via the Republic, in terms of a transport route, or using the common transit convention, which allows a hop, skip and jump under security through GB to Northern Ireland. In those cases, the initial medicine will not need to be decommissioned or made inactive, so, when it lands in Northern Ireland, it will remain active and be scannable by pharmacy to ensure the verification and authenticity of that medicine.

Q229 **Chair:** Would that scenario, were it to come to pass, be affected at all were the provisions of the Internal Market Bill to be prevailing at the time?

Dr Greville: No, we had a look at the Internal Market Bill and we did not see that it had any relevance in terms of the supply of medicines to Northern Ireland, so it will not be directly impacted.

Chair: That is hugely encouraging. Colleagues, I am looking at the time and, rather than having to cut away for our two minutes' silence, we are able to bring this morning's procedures to a close, so that we can mark, respectfully and quietly, our own observations on this Armistice Day. Can I thank colleagues for joining us and taking part this morning? Can I thank our two witnesses very much indeed? You have given us a lot of food for thought.

I must tell you that, having chaired a number of meetings involved with all sorts of things to do with Northern Ireland and the implications of Brexit, you have given us some very calm reassurance on behalf of those who live in Northern Ireland that access to vital drugs and medication will continue into next year. At a time when, as I said in an earlier question, people have so much to worry about, I hope that that will be a cause of rejoicing and pleasure, and one less thing for them to be concerned about at this juncture. Can I thank you both for your attendance this morning, the clarity of your answers and your courtesy to us as the Committee?