



Public Services Committee

Uncorrected oral evidence: Medicines security

Wednesday 12 November 2025

11 am

Watch the meeting

Members present: Baroness Morris of Yardley (The Chair); Lord Blencathra; Lord Carter of Coles; Baroness Cass; Baroness Coffey; Lord Laming; Lord Mott; Baroness Pidgeon; Lord Prentis of Leeds; Lord Shipley; Baroness Wyld.

Evidence Session No. 5

Heard in Public

Questions 54 - 69

Witnesses

I: Ian Wariner, Country Manager, Orion Pharma (UK); Darius Hughes, UK General Manager, Moderna; Paul White, Head of Legal, Besins Healthcare UK Limited.

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Examination of witnesses

Ian Wariner, Darius Hughes and Paul White.

Q54 **The Chair:** Welcome to this meeting of the Public Services Committee in our inquiry into medicines security. I welcome our three witnesses today and ask them to start off by introducing themselves; let us go from left to right, if that is okay.

Ian Wariner: Hello. I am the country manager for Orion Pharma UK.

Darius Hughes: Good morning. I am a general manager at Moderna.

Paul White: Good morning. I am the head of legal at Besins Healthcare UK.

Q55 **Lord Carter of Coles:** Good morning, and thank you for your time. This is all about resilience. We have had a lot of evidence. The DHSC, in particular, has written to us and said: "Manufacturing has been the most dominant root cause" of medicines supply issues in the last five years. How would you respond to that?

Ian Wariner: I would say, first, that, as a company, we agree. Overall, when we look across Europe, the situation is the same: manufacturing is one of the core problems. However, sudden increases in demand and supply are sometimes exacerbating factors. It is very complex; I do not think that we can ever pin it down to just one thing.

Lord Carter of Coles: Do you think that the information flow within our system, which is meant to be quite integrated, is sufficiently good? Can you see flaws in it?

Ian Wariner: There are definitely challenges around the way in which we report into the DaSH portal and the way in which DHSC then comes back to us. It tends to be a more reactive process because, until it comes to us and asks, "Can you supply more?", I cannot do anything. At that stage, it may well be too late. We then have to look at the complexity of our manufacturing and supply chains. How quickly can we turn things around? Can we turn anything around? There are many steps that we have to consider at that point.

Darius Hughes: I think that that is an oversimplification of the challenge and the opportunity. As a vaccines manufacturer—one that was part of a pandemic supply chain—we know that, when we put our minds to it and there is a burning platform, manufacturing really is not the issue.

The issue is complex. We are manufacturing complex biological products and complex pharmaceuticals that have to go through regulation, safety, effectiveness and testing. That takes a long time—as does flexing our manufacturing chains, which are global. For example, making a small change to one of my lines, such as packing a vaccine from one into 10, might take three years to get through.

So you cannot state that manufacturing is the challenge; it is about the system, end to end. When you look at the demand signal through to, in my case, a vaccine going into a person's arm, you need to look at that full supply chain manufacturing, demand signals and regulation as parts of it. It is a complex supply chain.

Lord Carter of Coles: I will hang on to that demand signal point because it is very important.

Paul White: We supply HRT medicines. The causes of the historic HRT shortages were multifactorial and included a sharp increase in demand fuelled by celebrity activities. There was the Government's *Women's Health Strategy for England*, which was published in 2022 and had a section on the menopause in it. There was also the introduction of prepayment certificates for HRT in April 2023, which enabled menopausal women patients to pay a one-off annual charge of £19.80 for all prescriptions.

In terms of what we could do better, obviously there is the DHSC continuation and shortages portal, but we need improved data sharing. In terms of the guidance and the portal, the EMA model is much more sophisticated. We could learn from that. I also think that, when the Government announce policy changes or guidance that could have an impact on prescribing, we could perhaps get advance notification of that before it comes so that we can plan ahead and maybe even collaborate with the Government.

Lord Carter of Coles: That was the case with NICE, was it not, in terms of HRT? Better signalling was needed.

Before we move on to the next question, I want to ask something quickly. These problems, such as balancing demand and getting signals, are what we might call day-to-day problems. What if we had a major incident and the flow of APIs were interdicted in some way? Take penicillin: if the one remaining plant in Europe goes, say, what is your general sense of how much risk that will carry? Somebody is going to ask a question on this, but how many people might die if these supply chains break?

Ian Wariner: I do not think that I can answer that comprehensively. What I can say is that our headquarters in Finland are constantly looking at that. They are looking at their country's resilience because we are a Finnish company, although we have carried out operations in the UK for 30 years. They are constantly looking at making sure that they have adequate APIs, but you cannot stockpile 10 years-worth of APIs, so there are certain issues there. I trust that they are looking at it at the right level but, if we want to make sure that we have the right supply for all of the other countries with which we work, that might need some work.

Darius Hughes: Vaccines are slightly different, again, because there is no API as such. Also, the manufacture of vaccines is normally a biological process, so you are talking about shortages in eggs, fermentation,

distilling devices or—as in the case of messenger RNA vaccines, which are what Moderna do—a shortage of DNA plasmids and some enzymes that would possibly go into those reactors.

There is a general concentration, shall we say, of those DNA plasmid manufacturers and those enzyme manufacturers in half a dozen places in the world. The supply chain is, therefore, quite dependent on those kinds of things, which is problematic. That is why, as part of the Moderna strategic partnership that we have with the UK Government, we will onshore some of those crucial parts in our vaccine production process.

Paul White: It is no secret that a lot of the API comes from China; obviously, that is a geopolitical risk of which we all need to be mindful. It does have a limited shelf life, of course. At best, we are looking to bring the manufacture of API in-house in Europe. That is obviously a way of securing supply in the medium term.

Q56 **Baroness Cass:** This might be a completely blind alley, but I wondered, Mr White, whether unlicensed or unregulated use of HRT contributes to shortages or whether that is a drop in the ocean. I mean its use in sports, gender dysphoria et cetera.

Paul White: I do not think it contributes to shortages, because we can build that into our forecasting because we can assess demand.

Baroness Cass: Except some of it is happening—

Paul White: Off-licence does happen.

Baroness Cass: It also happens with drug dealers and inappropriate sources.

Paul White: I am not sure that that is relevant to our products. I do not think it is. We can anticipate demand, based on all the market conditions, and make sure that the products get to patients on time and when they need them. What is difficult is when there is unexpected, unforeseen demand, because there are lead times and we need to plan for that, but we have extra capacity in our factories to meet demand.

Q57 **Baroness Pidgeon:** I want to pick up the issue of developing resilient supply chains, which you started to touch on. We saw the US Government issue an executive order in August about trying to be more resilient, which looked at stockpiling APIs for some 26 critical medicines. How are you incentivised—or are you incentivised at all—to develop these sorts of resilient supply chains for the APIs and medicines that you use?

Paul White: How are we incentivised generally? It is a very challenging environment in the UK. There is downward pressure on pricing via NICE, for example, and obviously VPAG is effectively a tax and clawback that manufacturers and suppliers do not have in other markets. For some of our products that are classified as older products, we are currently paying 35.6% this year on the clawback of sales to the NHS. That is going up to

36%. That makes it quite an unattractive environment, and there is always a danger that pharma companies will prioritise other markets.

Baroness Pidgeon: You talked about maybe bringing some API production into Europe, in the medium term. Would you want the Government to give you more incentives?

Paul White: Absolutely—there are not enough incentives in the UK, compared to other countries. There have been some high-profile withdrawals of investment in the UK from the likes of AstraZeneca recently. I do not think that it is an environment where pharma companies feel incentivised. In effect, we have to bear this extra tax that we do not have in other markets.

Can I just finish on bringing API in-house in our factories in Europe? We have manufacturing facilities in France, Spain and Belgium. In 2023, we opened a new facility in Spain with additional capacity. Certainly bringing API production and manufacturing into Europe—and/or the UK, ideally—would be great.

Baroness Pidgeon: Darius, do you want to comment on that? Do you think that the DHSC has really understood how to prioritise resilience into the supply of medicines procurement rather than just the costs that Paul mentioned?

Darius Hughes: Moderna is in a unique position. Post the pandemic, when we saw all our borders closing and a lot of our British-made vaccines stranded over in Italy, France and Belgium, the US closing its borders et cetera, the UK Government came to Moderna and asked us what we would see as the solution should another pandemic be called. That is when we started the Moderna strategic partnership, which is a 10-year partnership with the UK Government. That started in November 2022.

There are three pillars to that. The first is onshoring our full end-to-end supply chain. That involves building a manufacturing plant in Harwell, just outside Oxford, on the science park there, bringing onshore all our end-to-end supply chains and stockpiling millions of doses of all the raw materials required.

The second pillar is our pandemic preparedness plan so that, within 90 days of a pandemic being called, we would be able to supply 100 million doses of vaccine to the UK Government for whatever that pandemic was. That assumes that messenger RNA is the answer to a particular pandemic; we can never be sure exactly what lovely little bug will crop up and whether we can actually solve it with a messenger RNA vaccine. Should that be the case, the second pillar is a pandemic response plan. We are integrated into the UK Health Security Agency and have been part of Project Pegasus this last couple of months, which is a pandemic preparedness programme looking at our biodefence and biosecurity across government.

The third pillar is research and development. We will be investing heavily in research and development in messenger RNA vaccines here, using our technology platform. We have built a science technology centre next door to our manufacturing plant in Harwell. We now have around 160 employees in the UK working on science, technology and our manufacturing platform, and we are pandemic ready. On 15 September this year we declared that we would be, according to the contract, pandemic ready, should a pandemic be declared. Now we are ready to roll and produce those 100 million vaccines within 90 days.

Q58 **Baroness Pidgeon:** That is really fascinating and it is really reassuring to hear that that is going on, because a lot of us have been feeling concerned in hearing the evidence so far. You talked about stockpiling ingredients—if I can put it like that. What is your general view on stockpiling medicines to help us with resilience?

Darius Hughes: The only reason that we are able to stockpile our 50 million doses here in the UK is because we are being paid to do it, to be frank, and our onshoring. That is paid in return for buying our vaccines over the 10 years of this contract, so it is a quid pro quo. That is a totally different environment to our work generally. I will stick to vaccines, because that is what I know.

The only other manufacturer of vaccines in the UK is CSL Seqirus, which makes a flu vaccine up in Speke in Liverpool. The rest of the vaccines supplied to the National Health Service, around 40-odd vaccines across the paediatric and adult populations, are not manufactured in the UK. They are brought in from various parts of the world, so we are reliant on external partners for the supply chain.

Quite often you cannot stockpile vaccines; they do not have that shelf life and they are complex biological products to manufacture. The UK Health Security Agency gets over this at the moment by having a big fridge in Liverpool, where it stores circa 6 million doses of various vaccines, which is a stockpile of about six months. It has learned over the years that it can deal with short-term issues in supply by stockpiling, but that is quite an expensive process and, if you get a product out of stock for more than around six months, you start having problems. But, generally speaking, it has ironed out a lot of the supply chain issues by doing that.

Baroness Pidgeon: Ian, do you want to comment on this and the issue of resilience in supply?

Ian Wariner: First, 70% of our API comes from Europe and the US, so we have already done quite a lot to make sure we have got as much in-house in Finland as we can. In terms of the incentives to develop resilience, there are no incentives. The incentive is to make sure that we maintain patient well-being. That is what we are here as a company to do; we are all here making sure that patients get medicines when they need them. There are no incentives from the UK Government. It comes down to us needing to supply those medicines to patients, so that they

get them. Also, there is a reputational risk for us if we do not do it and cannot supply.

I think it is very important to look at the procurement piece, as well, and I have seen some of the previous witnesses talk about this. For procurement of secondary care products, your resilience for supply is now included. Do you have the stock? Do you have the capacity? That is really important alongside other issues such as sustainability.

However, in primary care products, which is largely where we are, whether for branded, innovative or generic medicines, there are lots of different factors to consider. Generic medicines have a very low price because of the huge competition, and that is generally a good thing for the UK but, ultimately, when the price keeps coming down, you get to a point where there is no money made and no incentive to keep supply. There is always a balance and no incentive from the Government there.

Q59 Lord Mott: I want to follow up on the incentive piece. In an ideal world, what sort of incentive would you like from the UK Government?

Ian Wariner: We have mentioned VPAG—the rebate that we pay—which varies between 10% and 35%, depending on the product. That is a very high rate; it is much higher than in the rest of Europe. Negotiations on that, so that there is less cost for us in running our business, are one thing.

Then you look at different medicines. Generic medicines are a very difficult area to look at because you are talking about pennies a pack in profit. We make a third of the world's methotrexate, for example, but we do not make a lot of money on it. If we did not provide that to the UK, there would be a problem.

There has to be a combination of factors. Perhaps look at a critical medicines list, then look at the very low prices of those critical medicines that fall under generics. What can you do to support industry not to take such a strong penalty as VPAG is giving?

Paul White: Pricing is the first thing—the actual price that you get when you sell your products. There is downward pressure on pricing. I have mentioned VPAG. On several of our products, which are deemed older products, we pay 35.6%, as I said earlier; that is going to 36% next year, in terms of extra tax to claw back. I also think that there could be better collaboration and planning, as well as discussions about how we can be incentivised; some sort of cross-functional body could look at this and at how we can be better incentivised.

Q60 Lord Shipley: We have been talking about incentives, but can I talk about the attractiveness of the United Kingdom as a location to manufacture medicines? You all have experience in this area. How could the UK retain innovative medicine developers more effectively? Also, how could the Government just do better at developing manufacturers to produce more medicines in the UK?

Paul White: I will pick up on innovation. Innovation tends to be thought of as new products, but you can innovate with older products. You can look at new formulations and excipients, and you can look at different dosing mechanisms. You can go from a tablet to a gel to an injection, so you might be able to innovate and come up with a once-a-month dose rather than a daily dose, but there are no incentives to do that.

We have mentioned VPAG and price pressures but, ultimately, it is about the patients in the UK who might not get the treatments they need because of the environment that we have in the UK. There may be other factors that affect why you would invest in certain European markets rather than in the UK. Obviously, Brexit makes it easier, with a single market; also, the labour costs may be cheaper. There may be more incentives to manufacture in other markets in the first place.

Lord Shipley: If I understand you correctly, innovation has many aspects to it.

Paul White: Exactly—it has many aspects.

Darius Hughes: I look at this almost as an innovation wheel. To incentivise manufacturers to come here, you need to start with research and development. We have amazing research and development in some of our British universities, institutions, the NHS and so on, but it is relatively difficult to get through clinical trials in the UK.

We saw Lord O'Shaughnessy's review a couple of years ago into clinical trials and how to drive that element. That is important because, when you start research in the UK, you start to get a patient base and an understanding of the market, but you also create data and evidence in the UK. That evidence and data can then be pushed through regulation, so the MHRA plays a crucial role not only in getting clinical trials registered and licensed but in the data that it sees. This world-leading regulator can then lead the way in regulating medicines and getting them through to NICE or the various other bodies that look at cost-effectiveness.

There is definitely some work that can be done on how NICE approaches its cost-effectiveness modelling and the quality-adjusted life years that it uses. It is set at £20,000 and has been since 1992. To put that into perspective, if you adjusted that against inflation until now, it would be £66,000 per QALY—over three times the amount. The reason why that is important is because that innovation gets into patients' arms; only then does it need to be made in the UK. If you can get it into arms and through the NHS, which is not a totally homologous institution—it is a very heterogeneous organisation; just because you can get it into one NHS trust or ICP does not mean you can get it everywhere, so there is some work to be done there—you would create demand and would need manufacturing. The Government could put some incentives in place then so that manufacturers think about bringing their manufacturing to the UK.

I think that we can focus on innovation, on those cutting-edge products and on that high-level science. Are we ever going to compete in huge-volume generic operations? I do not know—a lot of places in the world offer very cheap corporate taxes and so on—but I think that we could really lead the world in complex manufacturing and create that virtuous innovation circle.

Lord Shipley: Can you be clearer about speed? You were critical of the slow process, as I understood it. How would you speed things up?

Darius Hughes: Start on the research and development side of things. The MHRA is doing a lot of work on this: the new chief executive, Lawrence Tallon, is aware that, on average, we take twice as long to approve a clinical trial. In the US, you can get a clinical trial approval in around 30 days; in the UK, it takes 60 to 90 days. That is relatively short in the time span of a whole product, but it is important for UK competitiveness.

It can then take another two or three years to get through the regulatory authority, then NICE can take a couple of years to assess your medicine. Then it is another two or three years for the NHS to uptake. By the way, our manufacturing and supply chains can take three years to get going, so it can take 10 years from an innovation to reach a patient; that does not create a lot of incentive when, in the US, it might take three.

Lord Shipley: Ian Wariner, do you agree with what you have heard?

Ian Wariner: Yes, I do. They were really salient points. It is easier to invest in R&D than in manufacturing. We are just opening a plant, a research site, in Cambridge. We have invested £5.6 million and are just opening this month. That has been really important for us, but our manufacturing base is Finland and it is unlikely that there will be enough incentives around that at the moment. You have heard enough about VPAG; you know that pricing is not good for us.

It is also about the timeline that you have to go through. It is not about just identifying the molecule and getting through those regulatory hurdles; once you have your marketing authorisation, you have to get through NICE. Overlay that with VPAG: you get the first three years free, but that starts from when you get your marketing authorisation. If it takes a year to get through NICE, you will have lost a year for free, so you now have only two years before you are paying that VPAG. You have probably also been negotiated down to a lower price than you get through NICE because, as Darius mentioned, the NICE thresholds have been unchanged for 26 years. All in all, it is putting pressure on us not to be a good market.

Contrary to that, though, the UK is a big populous, so it is still an interesting market. That is why we still have pharma companies here: because there is a big population and medicines are required by patients. I do not want to be total naysayer about no one wanting to be in the UK, but there are challenges for us.

Lord Shipley: Is there a role for nearshoring or friendshoring, rather than just doing everything in the UK, if we had a group of companies with which we could work very closely?

Ian Wariner: We think that that is possibly more feasible than stockpiling. There are no simple answers to any of these issues—they will be long and protracted—but we have spoken within the company about whether that would work. It is more likely to work, because stockpiling would certainly not work for us.

Lord Shipley: Is there anything further that you would like to add about friendshoring or nearshoring?

Darius Hughes: I think that it was called the European Union, but something happened there a few years back.

Paul White: It is something that we do already, because our manufacturing in Europe is in-house; it is just the API that we need to bring in-house.

Q61 **Lord Blencathra:** I have a little question. Mr White talked a few minutes ago about a manufacturing company that changed from tablets to capsules or whatever. If, hypothetically, a company changes from a pill or tablet to a little silicon gel capsule, does it have to get new permission for that, even though it has the same ingredients? How long does it take—one year, two years?

Ian Wariner: Longer.

Lord Blencathra: Right. I was hoping the answer would be that I was utterly wrong.

Darius Hughes: I have a live example. Our vaccines come in multidose vials. We would like to get those into a single-dose vial or a prefilled syringe. Our drug substance manufacturing plant in Harwell makes a bag of stuff, to keep it simple, then we take it to a plant where it is filled and finished into those multidose or single-dose vials. In order to get that manufacturing change, we would have to create a whole new regulatory file, although it is the same stuff going in. We would also have to create a whole new manufacturing line because the multidose vials and syringes do not go on the same line. We would also have to do stability for that new line. We would have to go through all the regulation.

All of this is right. You cannot just throw it into a new thing and expect it to be exactly the same, but this goes all the way through the line. It will be a different cardboard box, which has to go through quality and assurance, et cetera. It is roughly three years to change from a multidose vial to a prefilled syringe.

Ian Wariner: I have a live example of a generic product that is currently on concession, which means its price is much higher. It is currently in the process; we cannot say that it has identical ingredients to what is on the market already. It is a long-term product and we will probably not be

able to launch until 2027-28 and will have to jump through lots of hoops. There is currently a shortage, which is why the price is higher. As Darius rightly said, we have to go through the right hoops to make sure that we have safe medicines.

Paul White: I think this is an opportunity for the UK since Brexit, because now we can do our own thing more. We have to do the right thing, but we could maybe do things a bit more efficiently and quickly, and that could be a competitive advantage for the UK.

Lord Blencathra: Please tell me that, if you change the shape of a paracetamol pill from circular to oval, you do not need to get permission. You do?

Q62 **The Chair:** Just leave it round in that case. Could we explore the regulator, the MHRA, a bit more? I am not quite sure how similar the regulatory frameworks are in all the jurisdictions that you work with. It would be great if they are all very similar, because that would be helpful. Is it about the contents of the regulatory framework or just the efficiency of the organisation—a sort of overcautiousness? Or is it a bit of both?

Paul White: It is a bit of both.

Darius Hughes: Regulatory agencies in general ask for slightly different things. All of us are global companies and we look at multiple different markets. You have to produce a global dossier which would have clinical trials work, your manufacturing process and a number of different subsections. Each regulator tends to use a slightly different dossier. Typically, we would have an FDA dossier, an EMEA dossier, an MHRA dossier, maybe one for Swissmedic or Health Canada and a couple more, and then we would vary it a bit. That is a little bit of complexity.

To be fair to the MHRA, it is doing a lot of work around that as well in the international recognition procedure. Where another agency has looked at the file, it takes a maybe less rigorous view because it knows that another regulatory agency has had a look. There is some work there. There is also some work going on between the agencies, some more friendly than others. In particular, the Commonwealth agencies are coming together and trying to get consistency in their filings. There is a little bit of work there.

And then, yes, it is process. A lot of that comes down to resource. The MHRA has done a lot in recent years since Brexit. It lost a lot of talent and has been under the cosh with the pandemic. I think it is coming out the other side now, but the number of assessors it had dropped by 50% and the number of staff it had when it moved the EMEA agency to Amsterdam dropped considerably. There is some catch-up to be done in human resource and financial resource to get the stuff through.

Q63 **The Chair:** I understand completely that generics and high-cost medicines are cheaper elsewhere, so you can absolutely see why we are where we are in terms of generics coming from overseas, but does it have to be a choice? I can see how that situation leads you not to focus

on the generics, but we need both, and the truth is that the generics are not being manufactured in this country. Given the geopolitical situation, in future that could be quite a serious problem. Is there a way out of that or will it always be, "We focus on the high end, the new drugs, the innovation", or we do not? I am not sure how one plays off against the other in reality.

Ian Wariner: I think it is complex. We all have different portfolios of products and sometimes you balance them against each other. You might be prepared to take a loss on one because you are making it up on the other, and ultimately you are trying to provide patient well-being. I think it comes back to the fact that there has to be better pricing available for our medicines in the UK to make us want to be here and supply them.

The Chair: And that is more in the one market than the other, which is a big driving factor.

Q64 **Lord Prentis of Leeds:** First, I have no interest to declare. Ian, before I ask about the area I am interested in, when we talk about onshoring being better than stockpiling—I think all of you believe that to be the case—what timescales are we talking about to move to onshoring and continental shoring? Is it just a pipe dream? Would it be a year? It would be very difficult for us to pick up if it is just in the ether.

Ian Wariner: To be honest, I am no expert on it, so I cannot say how long it would take. What needs to happen is that we understand what areas and medicines we need to look at. We need to look at the supplies and have a critical medicines list, and then we would have a Venn diagram and could say, "We need to talk to these people and see if they can provide more". My gut feeling is that it just needs to be a dialogue to start the process.

Paul White: Again, I can speak only for the Besins situation. We manufacture almost entirely in-house. The issue with stockpiling is that medicines have a shelf life, so you need to think about that. An alternative to stockpiling is advance purchase commitments, where you agree that you will buy a certain amount of product at different stages in the future. That is a possibility. I agree that there should be some sort of critical medicines list and we should look at how we can ensure continuity of supply. As an industry working with government, I would like to see HRT on that list.

Darius Hughes: I can give you a live example. We signed a deal in November 2022. Spades went in the ground in April 2023. We opened the manufacturing facility in September 2025.

Q65 **Lord Prentis of Leeds:** Okay, that is interesting. My question is around sharing of information on shortages. How effectively is information on shortages in stock shared across the supply chain and how do you believe it could be improved?

Ian Wariner: We have good links with the Department of Health and Social Care. When it approaches us, there are good comms there. Again,

I can give a live example. We were asked if we could provide an extra 100,000 units a month of one of our products because a competitor was going out of stock. I think the stock-out was for four months and then it was a delayed stock until the end of the year. We were in a situation where we had that stock available, so I have been able to say that we can do that. Then it gives its notifications.

There has been no change in our sales. That has not cost me anything because we had the stock, but if we were asked by the Department of Health to increase our supplies and, let us say, I went to Finland and said, "Right, let's get some more in there", I would suddenly be left with a few hundred thousand units that are not sold. It comes back to Darius's point. Is there any guarantee that, if you ask us for it, it is going to be used? That is not clear at the moment.

So we have very good comms with the department but they probably come a little too late, because it finds out about this only when it is reported by another company in the DaSH portal. It then reaches out to the other companies, we give the feedback, then it evaluates, and then it communicates. By then, we might already be in the shortage and patients are not getting it.

Lord Prentis of Leeds: Do you think it could be improved?

Ian Wariner: I think the only way you could look at improving it is by trying to get some more foresight on where the problems might come. If you take the HRT example, that caught us all very much unawares. We sell HRT as well. Both companies were involved in meetings with the Department of Health and the ABPI to make sure we worked closely. Everyone knew exactly what supplies we had coming in, so you could see how it was forecasting. But it kind of came out of nowhere, and for many companies that were sat on those meetings, their legacy products were just sat there and they were not investing; they were just flat-lining. If you have an innovative medicine that is a blockbuster, you are looking at constantly increasing your production, so you might be able to speed that up more quickly. But for an older medicine that is just sat there and that you have not been focusing on, there is inertia to get that moving again.

Darius Hughes: It is very different for vaccines again. We have a fairly good process and long-term horizon scanning; the Joint Committee on Vaccination and Immunisation does a horizon scan five years out of the vaccines that are coming, and then the UK Health Security Agency, in association with the Department of Health and Social Care, looks at policy and how it wants to get those vaccines in. It probably takes a few more years than I would like it to take, but eventually they come to a policy decision and the JCVI would make a recommendation, and then those are procured through central tenders and contracts generally for vaccines. Again, that process takes a couple of years to do. You may end up with the patient getting the vaccine five years after it has been licensed and registered, but it is a fairly robust, long-term horizon-scanning that seems to work.

The challenge is that if you have any out-of-stock, in-season or manufacturing challenges, then with vaccines you have no other option—you are basically out of stock. So if you take a flu vaccine, for example, they are all made in January for this season's flu; if you order 5 million doses and 5.5 million people turn up, you have 5 million people that are happy and half a million people that cannot have the vaccine, and there is not a lot you can do about it.

Paul White: I will make several points. First of all, there is already the DHSC discontinuations portal, which we have never had to use. In terms of the HRT shortage, there was a collaborative effort between government and industry, the HRT tsar et cetera, to meet that challenge. Our factories went into overdrive in terms of extra shifts and we also acquired product from other markets to meet the shortage. But I think it is informal and it seems to be quite reactive sometimes. Sometimes also, if another product goes out of stock unexpectedly, there is also a spike in demand on your product which you might not have anticipated. But, as I mentioned, the European Medicines Agency's European Shortages Monitoring Platform is a good model to look at in terms of something that we could do in the UK, and there are some very helpful guidance and documents in there and an obligation on market authorisation holders to report shortages proactively. We all want to serve patients and make sure that the right product gets to the right patient at the right time, but it needs to be a cross-collaborative effort between all stakeholders, and we should have a more formal mechanism than just the discontinuations portal.

Lord Prentis of Leeds: Just on the more formal mechanism, would better information-sharing deal with any of these issues of stability or lack of stability and resilience?

Paul White: Absolutely. All stakeholders should be quite open about the current circumstances and look at what could happen and what spikes there could be, and how we can minimise the impact on patients. At the end of the day, if a patient cannot get a product, that has all sorts of impacts on their personal, family and working lives. So certainly we could collaborate better.

Ian Wariner: On information-sharing, I would say it is about being able to understand what is in the supply chain. For all our products, we monitor very closely what we have in our pre-wholesalers and what is in wholesalers, and we probably have an indication of what might be in pharmacy. We manage that really carefully, and frequently we will inform wholesalers and say, "You're running low". If we are seeing a spike in demand, certainly through the HRT period, we are able to say, "You've got some in that depot and not in that depot—there's increasing demand there". So we are able to direct things a little ourselves. But, if all companies are monitoring their stock, to my knowledge there is certainly no central hub for looking at what there is in the UK, and that, alongside something like a critical medicines list, would certainly give an indication and enable us to say, "Let's have a look at this. Is there a way to foresee

that there might be a shortcoming and start dialogue earlier, rather than waiting until someone has reported that we are going out of stock in three months' time?"

Lord Prentis of Leeds: So, as far as demand forecasting is concerned, we do not have a system in place for the UK.

Darius Hughes: No, there is no demand forecasting system. The NHS is disparate and then the individual pharmacies that stock them—28,000 pharmacies or something—do not work together either. So you have different pockets. Quite often, when you get an out of stock it is not actually out of stock—it is in some warehouse, they have a million of them, and in another warehouse they have none of them, and the system does not let them talk to each other. So a centralised NHS is not a centralised NHS, and your supply chain is not centralised at all because it is very disparate between the different pharmacy wholesalers.

The Chair: We have had quite a lot of chat in our meetings about digitisation so that you can follow the product right the way through the system. We talked about barcodes; is that what you do within your own company? You do. I do not know if that is good news or bad news—it is good news for you. But say you did want a national system, does the fact that you all do it separately make it very difficult for us ever to get a national digitised system where it could go right the way through?

Darius Hughes: There is a central system in Europe but we opted out of it.

The Chair: You opted out of it.

Darius Hughes: No—the UK has opted out of the falsified medicines directive.

The Chair: Oh, sorry; we have opted out of it collectively. But could your own system that you have set up fit into an overall system? Would it not be difficult? It seems to be the obvious answer.

Darius Hughes: But they are probably all different again—the different platforms that they sit on.

Ian Wariner: Our system is based on communication with our wholesalers and getting information from them, and they all give information at slightly different times and in slightly different ways, so we have to package that up so we know what we need to order. It will not be easy sorting out demand for the UK. As head of UK operations, I find it quite hard working out what our demand is going to be over 18 months alone—it is an inexact science. That is then compounded when you look at the whole UK.

Q66 **Lord Carter of Coles:** Because you are international, are there markets you operate in where this demand forecasting is better, or is it just an inherent risk in an industry?

Ian Wariner: I would say that it is an inherent risk. Germany is a very strong tender market, so then you probably have a better idea of what you would do, but then when the tender drops, it might suddenly disappear, so that is not a solution either.

Darius Hughes: I do not think we are unique.

Lord Carter of Coles: Presumably you all maintain risk registers as international companies. Where does ceasing of supplies of the critical ingredients sit on that view?

Darius Hughes: It is pretty high. Certainly in vaccines manufacture, as discussed earlier, there is a relatively small pool to take from. So back-up suppliers, back-up back-up suppliers and all those things are in place to ensure continuity of supply.

Lord Carter of Coles: Is it the same for all of you?

Ian Wariner: I would imagine so but I would have to speak to headquarters to get an answer to you.

Lord Carter of Coles: Just drop us a note on what Finland does. That would be interesting to know; thank you.

Lord Blencathra: Can I go back to my paracetamol query? In your opinion, gentlemen, if all you are doing is changing the shape and it is still 500 micrograms of paracetamol, how long on average does it take to get that approval—one, two, three years—just for changing the shape?

Ian Wariner: I have not got that as an example. Thinking about the MHRA, on the whole, I would imagine that, if you can prove that you have exactly the same ingredients, that would be relatively quick.

Darius Hughes: A type 1 variation to a licence, once submitted, would take 90 days for approval from the MHRA.

Lord Blencathra: So it could be three months.

Darius Hughes: That is from the MHRA. But you have to get your dossier ready, your stability data—all the stuff ready—and once you have approval, you then have to do your manufacturing. Your minimum time, even on basic variations, is 12 months.

Q67 **The Chair:** I have just one more point of clarification. We have had an interesting discussion about stockpiling. Mr Hughes, I think you said that the vaccines are stockpiled. Is it because of the component parts that you are more able to do that?

Darius Hughes: The UK Health Security Agency centrally procures vaccines for the national immunisation programmes for adults and for children, and it holds a stock in its warehouse. The manufacturers would be part of a tendering process. Those tenders normally last two, three or four years and you would all go into a tendering process but, once you won the tender, you would get indicative supply for two years of that

tender: "We want 100,000 units every month", "We want 5 million doses in a winter" or whatever. That would be delivered to UK Health Security Agency warehouses, and they would try to keep six months' stock of those national immunisation programme vaccines because of supply challenges. They would also try to get more than one supplier, if available, so that you could have a little bit of a back-up. Then you have the same problem: if one supplier goes out, can you turn your supply chain on quick enough in the six months? But it mitigates some of that risk.

For us, with our onshoring, we would really like to work now with the NHS, the Government and the UK Health Security Agency to get those demand signals directly to our plant. We do have the capability, through digitalisation, to get a demand signal for a Covid vaccine and to make it within three months within the UK. Could we start to get a little bit more sophisticated with that? That is one of the projects that we are looking at working on.

- Q68 **Lord Prentis of Leeds:** This is an operational question. Say an essential medicine is no longer being produced in Germany but is being used in the UK on a regular basis. Who tells who that that medicine is no longer available? What is the chain that goes through to the patient that says, "You no longer can use that medicine"? Is there anything?

Ian Wariner: If you withdraw a medicine in the UK, you have to notify the MHRA, go through a process and give notice that you are going to withdraw, and the reasons why. We have done it recently for a product that just was no longer selling—there was not a demand for it. It was not a critical medicine and there were other options. I do not think there is a situation I know of where there is a critical medicine that is not being used elsewhere. I do not know whether that answers your question.

Lord Prentis of Leeds: Who tells the pharmacist?

Ian Wariner: There will be a chain of events. If we are withdrawing medicine, we have to inform. We will send notifications out to pharmacies that we are withdrawing a product from the market. That is my understanding of what we do. But they will be given notice and there will be alternatives.

- Q69 **The Chair:** When we do our report, we will give some recommendations to the Government. What recommendations would you like to see us put in that report?

Ian Wariner: I think you will not be surprised—

The Chair: Yes, I think I know what the first one is going to be.

Ian Wariner: Improving the pricing environment for us is the most important thing to do for our industry.

The Chair: It is that important?

Ian Wariner: It has such an impact on us at the moment. I know there were attempts to renegotiate with the Government, and that failed. It has a huge impact across all our organisations.

Darius Hughes: Resource the MHRA, both financially and in human resource, to ensure that clinical trials and regulatory approvals go through safely and effectively but as quickly as possible. Update the quality threshold for NICE and the JCVI to reflect proper inflation, therefore reflecting proper price and value of medicines. Ensure that the NHS is incentivised to use innovation rather than not to. There are whole gaggles of people in the NHS whose job is to reduce the use of medicines innovation in the NHS. Finally, incentivise manufacturers to onshore their manufacturing and supply chains through things such as the life science innovation fund, or the life science manufacturing fund—I get it wrong, but there is a fund. I cannot remember it.

The Chair: We know the one you are talking about. Mr White?

Paul White: Besins has already got the nearshoring piece, as I have mentioned. Initial pricing—the price at which you sell your products—needs to be reviewed, by which I mean the pricing mechanisms which we have discussed and how the pricing is set in the first place. Then there is VPAG, as I have mentioned. We also need to look at incentives in grants that are available to encourage investment in the UK, and at better cross-industry mechanisms and government industry mechanisms for securing supply.

The Chair: Thanks; that is a good lot of recommendations that you have helped us with. Thank you all for what has been a very informative and interesting session. We will close the session officially now. Thank you for your time.