Public Accounts Committee

Oral evidence: Price increase for generic medications, HC 1184

Wednesday 4 July 2018

Ordered by the House of Commons to be published on 4 July 2018.

Watch the meeting

Members present: Meg Hillier (Chair); Chris Evans; Caroline Flint; Gillian Keegan; Anne Marie Morris; Bridget Phillipson.

Adrian Jenner, Director of Parliamentary Relations, National Audit Office, Robert White, Director, NAO, and Richard Brown, Treasury Officer of Accounts, HM Treasury, were in attendance.

Questions 1–170

Witnesses

I: Mark Burdon, Regional Representative, North East and Cumbria, Pharmaceutical Services Negotiating Committee; Warwick Smith, Director General, British Association of Generic Manufacturers; and Professor Karim Meeran, Deputy Director of Medical Education, Imperial College.

II: Sir Chris Wormald, Permanent Secretary, Department of Health and Social Care; Steve Oldfield, Chief Commercial Officer, Department of Health and Social Care; Dr Bruce Warner, Deputy Chief Pharmaceutical Officer, NHS England; and Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency.

Report by the Comptroller and Auditor General

Investigation into NHS spending on generic medicines in primary care (HC 1122, Session 2017–2019)

Examination of witnesses

Witnesses: Mark Burdon, Warwick Smith and Professor Karim Meeran.

Q1 **Chair:** Good afternoon and welcome to the Public Accounts Committee on Wednesday 4 July—an auspicious day in the United States and an auspicious day, hopefully, in this room, as we want to get some understanding of how NHS spending on generic medicines has an impact on primary care and particularly of what happened at the end of last year, when the price of some drugs rose dramatically, causing real challenges for pharmacies in providing patients with what they needed, but also putting CCGs into a cumulative deficit of some £250 million by the end of the financial year. We have been puzzling through what happened and we want now to delve into why it happened, but not that so much as looking forward to how it could be prevented in the future. We recognise that it is not just what happens in the UK that has an impact, but the global market.

I am delighted to welcome our first witnesses—a pre-panel, really, to help us to get a bit of background and understanding before we question the Department. Professor Karim Meeran is a professor of endocrinology and deputy director of medical education at Imperial College London. A very warm welcome to you, Professor. Mark Burdon is the regional representative for the north-east and Cumbria on the Pharmaceutical Services Negotiating Committee, and Warwick Smith is director general of the British Generic Manufacturers Association. You all bring an interesting perspective, and I want to kick off with you, Mr Smith. Can you explain to us how generic manufacturers decide which drugs they are going to manufacture and how they change their minds—when they might shift production from one drug to another? What are the influences in that?

Warwick Smith: It is a complex process, but I will try to keep it short. Originator pharmaceutical companies develop a new drug. They get a patent on that for up to 20 years—more typically around 15. Once that patent expires, generic manufacturers can enter the market for the same product. Work needs to be done before they can launch the product. They need to develop it, to go through a regulatory process to demonstrate that it is equivalent to the originator product, and to get it authorised by the MHRA. Then they can launch the product on the market.

The factors that they will take into account, in deciding whether to go through that process and make that investment of time and money, will depend on issues such as the size of the market, the price of the product and the relative complexity or simplicity of it. That can involve the manufacturing process or the so-called pharmacovigilance process of monitoring it in use. It can involve the clarity of the patents around the product, because some products will have 60 or 70 patents, and if you're not sure that you have got all that right, you might find yourself in court.

For the majority of products—unbranded generics, if we stick to that broader category—the arrangement that we have with the Department of Health and Social Care is that we can launch at a price lower than the originator's price. Typically, for most products, competition will kick in quite quickly, and the market price of those products will fall, typically by 90%, up to 95%. So the argument around the economics and public policy of this is that you in effect pay off the investment for research into the new product over that 15-year patent period. Competition then comes in and you create the headroom for the next one.

Why would companies pull out? The market changes a lot. You might find there are different usage patterns, so what has been a volume product becomes a niche product. Prices will change with competition. If companies cannot make a profit on a product, they will look to pull out of it. Some companies will market themselves on having a full portfolio, so will stay there forever. Again, our arrangements with the Department of Health recognise that for the majority of unbranded generics—there are exceptions—the market operates as a commodity market, on supply and demand, so frankly, if the price goes too low, some manufacturers will pull out, the price will go up and they will then come back into the market. There is research, which we had done some 20 years ago, comparing the prices of unbranded generics with those of commodities—copper and so on—and the shape of the graph is exactly the same. The amplitude of generic prices is a bit higher, but the shape of the graph is exactly the same as for typical commodities.

Q2 **Chair:** Just to give us a flavour of how quickly a company could decide not to produce a drug, if you have put in the investment to manufacture the drug as it becomes a generic and you decide to pull out because the price has dropped, how quickly, typically, would a company then be able to go back into that manufacturing? There are obviously industrial processes that have to be gone through.

Warwick Smith: Typically, you would be looking at six months.

Q3 **Chair:** Wow. So if a company pulls out and the price goes up, and that contributes to the price going up on the market, it would take six months potentially to add some correction—

Warwick Smith: Absolutely. The complexity is really one of supply chain, so beginning with active ingredients for the product, which may or may not be made by the finished-form manufacturer. Typically, these days, the main supply of active ingredient is from China and India. You need contracts with those manufacturers to find the active ingredient. You then need time on your own production line, or to contract out to another production line. It is those processes that take the time to enter or re-enter a market, which means of course that manufacturers do not take an easy decision to leave, because they recognise that the coming back has its pains as well.

Chair: That is why I asked the question.

Professor Meeran: Although you say six months, it tends to be about two years, because if you want to launch the same drug, you first of all have to prove it is the same to the MHRA and you then need to store it for a period to prove that it has got a shelf-life, so by the time it comes to market it is about two years. So if the price starts to rise, the company putting the price up has a two-year window at least before there will be any competition. That is one of the reasons why the competition is not working—because of the two-year window. If I were a new company thinking, "I can make some money on that in two years", I know that in two years' time they will cut the price so I will not even enter the market because I am going to lose my investment. I think that is a problem.

Warwick Smith: That two or three-year period is the sort of period that a manufacturer that does not have the product takes to enter the market; the six months is taken by a manufacturer that has a licence and has been in the market, but wishes to re-enter.

Q4 **Chair:** Either way, it is quite an issue. What do you think, Warwick Smith, caused the spike in some of the prices going up so dramatically at the end of last year?

Warwick Smith: I think the main reason—most people are clear on this, and I think it was in the NAO Report—was that three manufacturers, two of them scale manufacturers, in effect ceased manufacture because of a regulatory intervention that caused significant shortages in the market.

It is worth recording thanks to the entire supply chain, not just manufacturers, because, in a relatively short period of time—I know at the coalface it feels longer—we have got back to the stage at which the work being done by the Department shows that there are no real shortages anymore. The market might be less fluid than it was, but the gap that was created seems to have been filled.

Q5 **Chair:** The graph in figure 4 shows the increase. As you said, there was a particular issue because of the regulatory element, but do you think that that could be replicated with other issues, such as pure competition? A company might decide to supply another country, for example, rather than the UK market. Or was it just a conflation of the normal market processes and that particular regulatory intervention?

Warwick Smith: I am on record as saying that we had a perfect storm, and one hopes that perfect storms do not recur frequently. I am too old to say that it will never happen or to give you a timescale, but regulatory action against four companies in total—two of our members who were scale manufacturers—is very, very unusual, so I would be surprised to see this recurring quickly. I have been in this role for about 20 years, and I have only seen this sort of disruption twice in that period.

Q6 **Chair:** Turning to Mr Burdon, you represent or are negotiating for pharmacies on prices. How did that impact on your members? Same question as I asked Warwick Smith: do you foresee this happening again?

Mark Burdon: I am a practising community pharmacist myself—I own a small group of pharmacies in the north-east—and I have not observed and am not hearing reports of patients going without medicines for any length of time, or indeed of patient harm. Much of that is down to the efforts of community pharmacists, who are applying workarounds—for example, the rationing and staging of supplies, or suggesting therapeutic switches to prescribers. Pharmacists of course have a duty to supply, which means that they cannot turn away prescriptions. However, our members—our pharmacists—are dispensing medicines often not knowing the price that they will be reimbursed for that medicine. Added to that is the financial pressure due to the Government funding cuts that came into force over a year ago. It is becoming untenable. The workload involved in sourcing medicines and communicating with GPs, patients and hospital consultants is vast.

I was contacted by the Sunderland local pharmaceutical committee, which represents pharmacists in that area, and in their letter they say that, "Significant resources and time was spent by community pharmacy contractors to source stock and ensure that patients received their medicines." We pick up thousands of reports through our office—the PSNC.

What has helped us in our work as pharmacists has been the relationship we have with GPs. We contact them a lot. Our GP colleagues have been extremely helpful in helping to work with us and bring about solutions.

Q7 **Chair:** Does that mean someone will contact a GP and say, "We don't have this drug. Can you prescribe something different?"? Is it as basic as that?

Mark Burdon: Yes. A very basic example would be when we cannot get the 20mg presentation of a particular drug, but we can get the 10mg one, so we agree that we will supply two of the 10mg tablets. On the other hand, it could be contacting an ophthalmologist when a particular eye drop is unavailable for an alternative.

Q8 **Chair:** So where you had shortages, your members were having to do that.

Mark Burdon: Yes, on a daily basis.

Q9 **Chair:** I will ask Bridget Phillipson to come in in a minute, partly because you have a geographical overlap, but we had some evidence from Mike Hewitson, who is a pharmacist, and he claimed that stock shortages were sometimes caused by rumours by wholesalers that resulted in a self-fulfilling prophecy, as pharmacists ordered several months' stock at a time. Is that a scenario you recognise?

Mark Burdon: Yes, rumours can go about, and they create a situation where people panic-buy. That is to be expected.

Q10 **Chair:** Do you have any role in your body to make sure that you send out messages to people not to do that?

Mark Burdon: It is not really in our remit.

Q11 **Bridget Phillipson:** In terms of the impact on pharmacies, what was the response of patients to some of those challenges, in terms of the interactions they had in community pharmacies with your members?

Mark Burdon: Some of them were incredulous. I remember telling a particular patient that I could not get a certain drug, and the response was something along the lines of, "Well, you're not much of a pharmacist if you can't get it," but generally, patients understood the situation. I can recall one case where a breast cancer drug was unavailable. We were able to get small supplies of it, so we rationed the product. We spoke to the patient and the patient's carer and explained that we could give a week's worth at a time, but we made every effort to fulfil the next supply, but of course that caused a level of anxiety and worry for patients.

Q12 **Bridget Phillipson:** We have seen coverage about the potential move to online pharmacies and the prospect of market entrants. What assessment have you made of the likely impact of that on community pharmacies? Is it an inevitable consequence of where we are? How can community pharmacies respond to that?

Mark Burdon: PSNC represents all community pharmacies in the country, including some of those distance pharmacies. Our position is that as long as the competitive market remains, that is in the best interests of patients and the NHS. We support the broad range of different providers. For instance, a distance supplier may be advantageous or convenient for certain patients.

Q13 **Bridget Phillipson:** In terms of where you see things next year, what is the situation likely to be then? Will any additional changes need to have been made?

Mark Burdon: If there was an easy solution, we would have found it. PSNC has a constant interaction with the Department of Health and Social Care on the operation and the improvements to the price concession system. Progress is not easy because of the complexity associated with this particular mechanism, and the number of stakeholders involved, including the NHS. We hope we can prevent a recurrence of the situation we saw in 2017, but it has proven to be really tricky. Despite our best efforts, we have not found a solution that works.

Just to add to that, this is not just a UK problem; it is a worldwide issue. When I talk to colleagues in North America and Australasia, they tell me they suffer similar problems with stock shortages. They have not been able to find a satisfactory solution either.

Q14 **Anne Marie Morris:** Professor Meeran, I am going to ask you for your view in two respects—first, as a practising clinician and, secondly, as an academic who has written quite a bit about generic drug pricing and the need for reform. Can we start with your role as a clinician? Can you explain, for the benefit of the Committee, what the impact on the patient is of generics and the way we manage them in this country, and the

specific situation we found ourselves in in 2017, with the hike in prices and drug shortages?

Professor Meeran: It is surprising that you say 2017, because this has been going on since about 2010 with different drugs. I know it has really come to a head, but it is not a new problem. It happened with phenytoin in 2012, when Pfizer, who were selling it for £2.80 for a month's supply, pulled out. Another company, Flynn Pharma, took it on and put the price up to £67 a month from £2, and the NHS spend went up from £2 million to £50 million. We had been doing that, and then in 2016 the Competition and Markets Authority recognised that there was clearly a problem and fined them. Three weeks ago, the CMA lost an appeal, which essentially means it is okay. Competition clearly is not working if the CMA cannot intervene.

In terms of patients, if you are an epileptic, phenytoin is a drug that you need. There are alternatives, but the things about patients with epilepsy is that they are stable, and if you are forced to switch brand or drug, you might destabilise someone's well-controlled epilepsy. That is the kind of thing that worries patients if a drug suddenly disappears. Of course there are lots of other anti-epileptic drugs we could use, but if you are stable on one drug, it is not right to force a change. We have to do that sometimes because the drug is not available or the price goes up.

There was an interval between the low price and the high price when it was not available. What happens is that one company pulls out, then there is a little panic as the supply disappears, then after a short interval we get another supply at a higher price. That is a big issue for patients.

Q15 **Anne Marie Morris:** How many patients are affected by this, typically?

Professor Meeran: In the case of phenytoin, it is a huge number.

Q16 **Anne Marie Morris:** Huge is?

Professor Meeran: In our hospital, there will be easily 200 patients. I don't know how that would expand out nationally. If the budget has gone from £2 million to £50 million, that gives you a feeling for how much it is used. The drug I work with is a steroid called hydrocortisone, which is essential for patients who have got no adrenal glands.

Chair: Figure 8 on page 24 covers some of this stuff.

Professor Meeran: Hydrocortisone was sold by Merck for about £1 a month. They pulled out in 2008, and then by 2010 it was £50 a month from Auden Mckenzie. I then started writing things in journals, because it was my drug—we were using a lot of it. It got a lot of publicity in various newspapers, but despite that the price kept on going up. The company was not affected at all by the negative press, and there was no competition at all.

Q17 **Anne Marie Morris:** In terms of your patients, were you able to have any advance warning about what might be going on? Was there any general communication between those of you in endocrinology? Could you see it

coming? Was there anything from the Department of Health?

Professor Meeran: What is really fascinating is that I was unaware of the price rise, so I kept prescribing it. My pharmacy had an overspend, and I was unaware of it. I became aware of it when we had a patient who was not NHS-entitled and was brought in as an emergency. I said to her, "You need some hydrocortisone," and she couldn't afford it because it was £100 a month. I was really shocked. I said, "There's an error down there in the pharmacy," but, no, it was £100 for a month's supply, rather than £1. I then looked into it, and that is when I started doing all this work.

Q18 **Anne Marie Morris:** Do you think there is an argument that we are not well prepared for these sorts of crises, and that there needs to be better communication, whether it is from the pharmaceutical piece to the practitioners, or whether it is from the manufacturers or NHS England. Somebody, somewhere must have a clue that there is going to be a problem well in advance of it hitting you. You are trying to prescribe something to the patient, which means that the pharmacy has to prescribe something at an abominable price.

Professor Meeran: That is absolutely right. It is happening at the moment with another drug, called Pregnyl, which is now not available.

Q19 **Chair:** What is Pregnyl?

Professor Meeran: Pregnyl is an injection that men with infertility need, if they have got pituitary failure, to introduce spermatogenesis so that they can have children. That drug, HCG, or Pregnyl, as it is called, disappeared about four months ago. It is just not available. There is no licensed alternative, so we are now being forced to use an unlicensed preparation—we have got permission; we are importing it from Italy—called Gonasi, which is not the same drug and is much more expensive. That is an issue, and that is happening now.

Q20 **Chair:** So despite that shortage, no manufacturer is stepping up to do that.

Professor Meeran: No. There is no one else who is making any Pregnyl.

Q21 **Anne Marie Morris:** Do you think, in terms of advance warning, that is better coming from the pharmaceutical association or from the manufacturers, or from NHS England? Who is likely to have the information first?

Professor Meeran: I suppose the manufacturers. I phoned up the company that make Pregnyl and they said they have stopped making it as a commercial decision. It was a planned stop, and they are not planning to restart it. I hope someone else comes into the market and makes it.

Q22 **Chair:** And presumably, Mr Smith, they do not have to tell anyone when they stop making it. They just decide to do that; or, ethically, do they alert people like Professor Meeran and colleagues?

Warwick Smith: Manufacturers do need to notify the regulator if they are withdrawing a product from the market.

Chair: So there is a communication gap there.

Warwick Smith: And we have what have just stopped being voluntary arrangements and become statutory arrangements with the Department of Health and Social Care that we are required to notify the Department if we have a shortage, or impending shortage, if we can see it coming ourselves, of products.

Q23 **Anne Marie Morris:** Mr Smith, I know this is a new regulation under the Health Service Medical Supplies (Costs) Act 2017, which has only been in force—

Chair: It is not coming in yet—it is going to become mandatory.

Anne Marie Morris: It is now—1 July. So in a sense it is quite hard for you to work out exactly what the impact will be, but, as I understand it, the obligation is six months' notice. I suspect that for some drugs, given what we have heard about the time to get another business to do it, that is really not enough. Also, as far as I can see, there is not much by way of penalty if you do not say to the NHS "I am stopping production". I guess my question to you is what on earth the NHS is supposed to do. Presumably it has some idea—I would like to think—of the key drugs we must have. What can it do, given its global market of supply and demand, to make sure that drugs that are crucial for Professor Meeran and his patients are actually going to be available?

Warwick Smith: I think it is important we distinguish between different circumstances that lead to these occurrences; and, to an extent, we have conflated a number. So for the vast majority of generics competition keeps the market price down at below £1, so competition does work. There have been some products where the competition authorities are investigating and, forgive me, while those investigations are under way I cannot really comment on those, but there can be reasons for significant price increases. There might not be—I do not know. We need to see the outcome of those investigations. I do not know the circumstances of the last product that Professor Meeran mentioned.

What I would say is that most shortages—again, for the majority, I am talking here about shortages that happen rather than decisions to withdraw from the market—occur because of third party events. So smaller shortages were dealt with in the past: Mumbai port went on strike for a week. There were no supplies of active ingredients coming from India. That created a small shortage. Typically, our own quality mechanisms show that we are unhappy with a batch, so that batch is junked, and we remanufacture. So small shortages, if I can put it that way, occur without any warning for manufacturers, for anyone, as much as pharmacy or patients. Just in passing, I do not really think it matters, the size of the market; I think if we fail to serve one patient that is a failure, and I do not think we should say "How many patients are being served by this medicine, or not?" Our job is to produce high-value, high-quality products for patients. If we fail in any one of those three points, frankly we have failed.

Q24 **Anne Marie Morris:** But then there is a challenge, isn't there, because it is a global market and you are the UK manufacturers association? There is a whole global production system producing all these medicines, and you have to look at what they produce that we use, and what you produce and we use, in terms of meeting the need. What can the Government do, or what advice can it give you, to try to ensure that we are well aware of what UK plc's patients need, whether it is manufactured by your members or by others, so that you, as the UK manufacturers association, can do something about this and Professor Meeran and his patients are not left short?

Warwick Smith: Most manufacturing these days is done at least on a regional basis, if not on a global basis. Most of my members are part of global or European businesses; they are not UK businesses. The Chair touched in her introduction on the point that being part of that global market means that UK subsidiaries have to get supplies from a European operation. Typically, companies will manage that by looking at the level of demand. If there is a shortage, frankly, price in a particular market will come into play.

There is a direct relationship between prices and the degree of shortages. Countries that have higher prices tend to get fewer shortages. That is partly to do with resilience, and it is partly due to distribution decisions. That is very different from a manufacturer taking a decision to withdraw from a market. That would typically be, as Professor Meeran said, where they cannot get a price that makes the manufacture of a particular product economically sustainable. That can be discussed with the authorities. If it is a branded product and price is controlled, it can be discussed with the authorities and arrangements can be made. If it is an unbranded generic, we can put the price up. That does lead to criticism, and I am aware of some companies that have decided to withdraw from the market rather than take that criticism.

Mark Burdon: To add to that, from a pharmacy point of view, I know that we have some of the very cheapest generic medicines in the world in the UK. These are high-quality medicines. From our perspective as pharmacists dispensing these medicines, the system generally works very well. It is an effective and efficient market. We dispense over 1 billion prescription items a year, with cost savings, we estimate, in the region of over £10 billion over the last decade. We believe it is important that we protect this competitive market where we can.

From a public health perspective, there are benefits. Millions of patients are provided with vital medicines in this country that they could not get if they were very expensive. For example, millions of people are on statins—treatments to reduce high blood pressure. The system is delivering large-scale improvements in population health. When I qualified as a pharmacist in 2000, a statin was £30 a box. It is now less than £1. Consequently, the people who were previously treated with statins typically had a particularly severe type of hyperlipidaemia. Now we can treat vast swathes of the population using effective medicines for a very, very low cost. Overall, it is a functional market.

Q25 **Chair:** But if the cost went so low that manufacturers did not stay in the market, could there be a false economy, in a sense?

Mark Burdon: It is important to reach a balance between medicines being too expensive and being so cheap that suppliers are driven away from the UK market.

Q26 **Chair:** Professor Meeran, you have looked into what could be done. Obviously, as Anne Marie Morris highlighted, there have been changes in the law to make manufacturers tell the Government when something is being reduced, but the sanctions are not necessarily there. What do you think would make things better? The Government cannot completely manage this market—it is global. What would make it better?

Professor Meeran: When I qualified as a doctor in 1980-something, a lot of hospitals made a lot of their own drugs. This was a long time before the MHRA were as involved as they are now. The WHO have made a list of essential drugs for any healthcare system. Hydrocortisone and phenytoin are on that list. Drugs like that should be very cheap. There is no research and development in generic drugs, because they have been researched and developed; they now just have to be manufactured and sold. The cost of those drugs should be a lot lower. I know you say the mean cost in the UK is low, but there are too many exceptions. If you have 10 drugs, of which nine cost £1 and one costs £600, it is the £600 drug that will have the major effect on our mean spend.

All of the drugs on that list should be very cheap to make. We should look at whether we can make it within the health service and have a body that makes it, and not to make a loss but to break even. We do not actually know the cost, and it is difficult to work out how much it is. We import stuff from China and India. Why don't we make it in the UK and sell it and use the NHS as a bulk buyer rather than go through wholesalers, because the wholesalers are splitting the NHS?

Essentially, if I prescribe an expensive drug, the company often offers the hospital discount rates if I prescribe drug x rather than drug y, but when I go to the general practice to continue the drug, the price is much higher. If the NHS did all the manufacturing of just those essential drugs—not new drugs or developing new things but just that small list—I think we could save money.

Q27 **Anne Marie Morris:** Professor Meeran, you are not the first person to suggest that to me. It is about manufacturing our own or it is about bulk buying our own where it is absolutely critical. Physically, how would we do it? Where could we do that and how should we fund it?

Professor Meeran: The funding won't change. Instead of the hospitals buying it from another company, they would buy it, let us say, from NHS plc, and NHS plc is very large. It is on many, many sites. We could, for example, have one trust that started to make hydrocortisone and another trust that started to make phenytoin, and just the essential drugs on the WHO list. We could have such a supplier that was not driven by the market and would not lose money. Let us say Guy's and St Thomas' were

making hydrocortisone for the country, for the NHS, and for all the GPs and hospitals, then all of the other trusts in the UK would purchase it at the cost price from that trust. Then another trust might make phenytoin. We would have a system across the NHS that would be very secure, because they would give us plenty of—

Q28 **Chair:** Have you looked at what the cost would be?

Professor Meeran: Others have done that. I think for the *New England Journal* someone has read what I have written and looked at the American market, and they have worked out that it would cost $200,000 per drug to start, if it was generic, without any investment in research and development, because these are drugs that have been researched and developed.

Q29 **Chair:** I think Great Ormond Street produces its own patient nutrition, whereas other hospitals buy that in privately. That is one specific example. Do you know of any hospitals that produce certain things, and do you know what the relative costs are?

Professor Meeran: There are drugs such as magnesium glycerophosphate that we get from St Bart's. They make it locally. It is very cheap to make. Magnesium is something that is difficult to make in that particular format and not well absorbed.

Q30 **Chair:** So they make it and they have had to absorb the set-up costs themselves.

Professor Meeran: They seem to have. They basically sell it to all of us at a very low cost.

Q31 **Anne Marie Morris:** What about the ingredients? Will there be any challenges in trying to get the ingredients?

Professor Meeran: That might be a problem because people seem to import a lot of them from overseas. But we should think about investing and making them ourselves. Many drugs are also made in the UK and many are made in Italy, or elsewhere in Europe, and imported.

Q32 **Anne Marie Morris:** So we have the capacity, the ability and the knowledge to make this a reality. It is just about the Government's will to make it happen.

Professor Meeran: I think so. The Wellcome Foundation was originally a drug company, Burroughs Wellcome, and they used to make drugs for the NHS. They have disappeared now, but the Wellcome Trust gives lots of money to research. That is an example where it can happen.

Q33 **Anne Marie Morris:** Is this something that in any event we ought to look at doing more of, given that with Brexit we still don't know the future and currently many of our drugs are manufactured and distributed across the sea in other parts of Europe?

Professor Meeran: I think it would be very wise to have a UK source entirely sourced, manufactured and sold within the NHS.

Q34 **Chair:** Would you assume that the NHS would have to buy it from that

source? Mr Smith is representing people who would also be trying to compete with the price that the NHS might come up with.

Professor Meeran: Competition should work. I am not against competition. I would be happy if they could make it and sell it at a price cheaper than the NHS. I don't think anyone should be forced to buy it.

Q35 **Chair:** The NHS could decide to pull out of the market. This is my point. If you are going to enter a market as the NHS, you will either have a monopoly purchaser—some of the NHS bodies—or you will be competing with Mr Smith's private sector members who have slightly different motives. Your motive is to provide medicine, but you know what I mean.

Professor Meeran: I think the overall effect will be that drug prices will fall, which I think will be good for the taxpayer.

Q36 **Chair:** Mr Smith, do you want to comment on what you have heard?

Warwick Smith: I have one correction and a couple of points. Actually, manufacturers do have to undertake research and development to bring the product to the market. It will take 12 to 18 months, and £2 million to £5 million, rather than the longer period that originators producing a new chemical entity will need to commit, but there is a significant investment at that point, when they come to the market for the first time.

The bottom line here is that by common consent—all the various publications and research documents that you read—we have if not the cheapest then among the cheapest generic drugs in Europe. The market depends quite a lot on active ingredients coming from India and China in particular, and there is a particular concern about the lack of alternative supply. There are many finished-form manufacturers operating in the UK—

Chair: It seems that we have got a market here. Whether or not Professor Meeran's idea takes root, you have still got all the challenges that are outlined, which seem to be outside the control of the NHS, or indeed any purchaser.

Q37 **Caroline Flint:** What you were saying, Professor Meeran, was very interesting, but if it is such a good idea, why has it not got more traction?

Professor Meeran: That is a very good question. I think we have too much faith in competition, and competition is definitely not working, because you can see in the case of hydrocortisone that there is a company in west London that has launched a supply of hydrocortisone for £9 a month and it is not being bought because of various regulatory issues. Auden Mckenzie's price of £100 a month has come down to £32 a month, but the company selling it for £9 a month is not selling any because—well, I can't explain it. I can't explain why the wholesalers are not buying the cheapest products.

Q38 **Caroline Flint:** Have you got an answer, Mr Burdon?

Mark Burdon: Yes. Just to provide some clarity, the competition in the market on hydrocortisone itself has worked and the price has dropped over the last—

Professor Meeran: Not to £9, though. I know that company is making it for £9, and it is not selling any. It is very good—I have seen it on the internet. They have published; they have launched. It was very well planned. Lloyds and Boots are only buying it from the other manufacturers at £32, which is the tariff, when they could buy it for £9 and save a lot of money for us.

Q39 **Chair:** Mr Burdon, have you got pharmacies tying themselves into long-term purchasing deals with some manufacturers?

Mark Burdon: No, the system works by a level of retained margin within the system of £800 million. We have put a lot of detail into our submission to the Committee, which explains things. It would take quite a long time to go through it all—

Chair: No, we have got the details here.

Mark Burdon: Essentially, the competitive market and the diligent purchasing by community pharmacy is what drives the price down over an extended period of time. I think that we have to take the long-term view and accept that occasionally there will be blips here and there, but overall in the long term the competitive market should work, and it largely does work, to protect the interests of the taxpayer.

Q40 **Caroline Flint:** I am not sure whether you answered Professor Meeran's question—it is quite interesting to watch you discuss it among yourselves, actually. He asked why this particular drug was not being bought at a lower price—

Mark Burdon: I am. In my case, I am buying it at a lower price and these prices are then monitored and measured and taken into account when the total drugs spend is calculated. The downward pressure is happening. Professor Meeran's experience is one thing, but my experience of purchasing and procuring these medicines is that we are buying the cheaper medicine.

Professor Meeran: Can I just come back on that?

Chair: Yes, Professor, and then I will bring Mr Smith in.

Professor Meeran: Charing Cross Hospital gets all its drugs through Lloyds Pharmacy; that is its wholesaler. I went to our pharmacy and asked, "Can you buy this cheaper drug?" They replied, "Well, Lloyds is only selling us—only supplying us—the more expensive option, so that is the one we are going to get. We can't get the one made by GENESIS Pharma." They are going through the wholesalers, who are controlling it.

Q41 **Chair:** I am impressed, Professor Meeran, that you actually know the price of drugs, because most of us will know doctors—I speak as someone from a family of doctors—who very often, certainly in the old days and certainly even now in hospitals, would not know the price of a drug that they are prescribing. Do you think there is a gap there, so that if more clinicians were challenging this and saying there are alternatives, and looking and pressurising, as you are now doing, would that help, as

one of the aspects of this very complex picture?

Professor Meeran: I think it would be very helpful. I only know this because I have looked into this area—not just for today; I have been working on it. You are right. I only discovered it when the patient told me that they couldn't afford it, as I described earlier.

Q42 **Chair:** Do you think there should be prices on everything that is supplied in an NHS hospital, even to NHS patients?

Professor Meeran: That has been suggested. I have heard it being suggested in Parliament, in fact.

Q43 **Chair:** A consultant told me that in America, because of the way it is funded—it wouldn't be the same for us—everything has a barcode so you know exactly what a patient is costing. That would be anathema in a health service that is free at the point of delivery, in a sense, but would something like that, which enabled you to record what the costs are and make judgments about whether a drug is the right one, help?

Professor Meeran: I think you need to be a bit careful. It is important that we know the costs, but patients all believe that good things aren't cheap and cheap things aren't good. That is an important thing to bear in mind before you publish the prices too widely.

Q44 **Chair:** That is just for clinicians to know. I am not asking you to cast aspersions on your fellow clinicians, but do you think that in a typical hospital most consultants at a high-up level, when they are prescribing or guiding junior doctors and nurses on what to administer to patients, would know the costs? Would they have any idea?

Professor Meeran: I am absolutely sure that they do not. On my ward rounds, I regularly ask people. We look things up when we prescribe them, and last week I discovered to my horror that dexamethasone had gone up fiftyfold. I was unaware of that, but it happened four years ago. We don't know the drug prices we are paying every day.

Q45 **Caroline Flint:** I am interested in the clinical side. Perhaps you can't answer about GPs, but how much do clinicians choose drugs because the drug rep has been to see them and said, "This is a good drug. We want you to use it"? How much transparency is needed to ensure that people are not sadly influenced by a particularly tempting promotion? I am trying to choose my words carefully.

Mark Burdon: Can I answer that one, please? From a primary care point of view, clinical commissioning groups monitor the prescribing of medicines. Very detailed information is made available to GPs. In my experience as a community pharmacist, I frequently point out to GPs when something is expensive, and so does the CCG. It has IT solutions that pop up and tell them to prescribe something that is a bit cheaper. Perhaps the problem in secondary care is rather different from primary care, but a huge amount of data is made available to us, and it is used to drive down costs.

Q46 **Caroline Flint:** Do you believe that, compared with, say, clinicians working in hospital, GPs are more aware of the cost of every drug they are prescribing?

Mark Burdon: GPs are very aware of the cost, yes.

Q47 **Caroline Flint:** And is there enough transparency at a local level so that other GPs, other organisations or even MPs can look across the piece and see the difference between one practice and another on particular types of medication for common ailments?

Mark Burdon: Yes, there is data—I can write to you, Chair, if you want the web link to it. A lot of information is publicly available. I practise in primary care, so I can't comment on the hospital sector, but I am guessing that there are also systems in place to monitor efficient prescribing in secondary care.

Warwick Smith: The two systems are very separate. I was going to make a similar point. In secondary care there is a tendering system by NHS England, and the tender award prices are made available on their website. It is easy for clinicians to see, but I agree that, in primary care, GPs are more responsive.

To make one further point on the recent discussion, I am slightly frustrated, because I can't talk about the products that are before the competition authorities.

Chair: We have got three examples of recent ones.

Warwick Smith: We would never defend what has been called price gouging—in other words, putting prices up for no good reason. I can't say any more than that until those cases are resolved. If you want an idea of how the market works, we looked at the actual sales prices of the majority of products before, during and after the recent turbulence. The average factory gate price—what my members are actually charging—at the beginning of last year was 93p. It went to a peak of £1.13 at the height of the disturbance, and it is now back to 99p. So you can see that competition does kick in when that turbulence goes away.

There will always be outliers. The competition authorities have always been there. Our arrangements with the Department of Health on pricing have always agreed that that backstop is there. What we have now with the new legislation is the ability for the Department to get better information and interrogate individual product prices more readily and effectively than they have done before without automatically going to the backstop of the CMA. I think that is very important.

Chair: I will have a question for you all on data in a moment, before we finish, because we do need to move on, but Ms Phillipson is next.

Q48 **Bridget Phillipson:** I want to turn again to the issue of GPs. Mr Burdon, you have talked about prescribing, but equally we hear about patients being given repeat prescriptions and ending up with relatively large

quantities of medication that they do not really require. What more needs to be done to bear down on that? When patients need their medication reviewing on a regular basis, where does the responsibility for that rest?

Mark Burdon: Ultimately it is the GP who prescribes the medicine, but the community pharmacist can have input in a number of ways, such as through the medicines use review service, which has been operating since 2005. There is also the new medicine service, which came in more recently. Our position is that community pharmacy could do more to help patients to understand the use of the medicines that they take and how those medicines can be used best.

Q49 **Anne Marie Morris:** Mr Smith, I am interested in what you say, because the new regulations that require this transparency came in only at the beginning of this month. I am not convinced, from all that I have heard, whether it involves hospital doctors or GPs, that the information that you talk about is readily available. My question, however, is this. Even if these new regulations make that information available, it is limited, because it comes in blocks. That is one thing. Secondly, as far as I can see, to make your members divulge it, there really isn't much of a penalty. Thirdly, unless there is an obligation to buy cheapest, all the information in the world is not very useful, particularly when you have things that are off tariff—specials and some of the generics.

Warwick Smith: I can't really talk about specials, because they are not within my remit. My members, with one or two exceptions, have already been providing the data voluntarily to the Department of Health, which is how they calculate the category M tariff reimbursement price.

Q50 **Anne Marie Morris:** But that is fixed over a period of time. It is not as if there is a general flow of information so that a prescriber knows.

Warwick Smith: Well, that information flows four times a year; it is quarterly. There are provisions in our current voluntary arrangements to make that monthly or even weekly if things are happening in the market that make that a more sensible way of behaving. My members have about 85% of the market. We have been providing that data already. We welcome the new powers, because they will bring into that mix companies that have not been providing the data voluntarily. I think that is important. I think the Department will now be able to track, almost, individual products throughout the supply chain, so they can see what is happening at the different stages, which is important. They will be able to see if product is going "missing" within the supply chain, which is important.

The bottom line comes down essentially to two facts. Overall, we have the most competitive market in Europe and the lowest prices. For outliers, we needed better systems to deal with them. We thought the Department had the powers; they felt they didn't. They have now reassured themselves that they have those powers, and we can use those going forward, so I think you will find that the sorts of issues we are talking about, for the very small number of products that have gone to the CMA, will be able to be resolved more easily, administratively, by the Department, and if they

can't be, they can still go to the CMA. So it is a much more efficient way of dealing with these outliers, and in a way that does not prevent manufacturers from increasing prices to stay in the market if that is the choice; that can then be assessed.

Q51 **Chair:** Well, there is a difference between increasing a price by 10p and increasing it five-hundredfold or in fact several-thousandfold, as we saw in some cases. Professor Karim Meeran has highlighted what he thinks could be one of the solutions. You might want to add something else. We have the Government witnesses in front of us next; what couple of things do you think Government could do to make sure this does not happen again? Can it do anything, or is it powerless in this global market that we have discussed?

Professor Meeran: We need to look at the competition. I don't think the sector would say, "There will always be outliers." If you have 800 drugs for £1 and one cost £1,000, the mean is still £1, but the outlier vastly increases the total budget, so the outliers are the problem. I don't think you can say that we have got the best market in the world on average.

Q52 **Chair:** What do you think that the Government can do about that? We have heard your treatise on NHS manufacturing. I think Moorfields—there are other examples—does that as well. Is there anything else that Government could do?

Professor Meeran: We seriously need to think about making it in the UK and in the NHS.

Chair: And clinicians knowing the price would be helpful.

Professor Meeran: Make sure we are aware of the price, yes.

Mark Burdon: The current system obviously on the whole works; it provides a competitive market that delivers some of the cheapest medicines in the world, so I think we have to protect that in the longer term. From a pharmacy perspective, my colleagues are saying that they need better access to information and more timely pricing data. Further honing of the system we have at the moment is absolutely necessary, but that work is already under way between PSNC and the Department.

Warwick Smith: Transparency—shining a light on everything that is going on, so if something is going wrong, we can do something about it. That is the most important thing. Overall, the UK is a net exporter of medicines but a net importer of generic medicines, and that is simply because we cannot make them cheaply enough here to compete with prices that come out of other markets, be they central Europe, India or China. I'm afraid that that is just the commercial reality, unless there is some public policy decision to change that.

Q53 **Chair:** So there is no provider of last resort in the UK if the market dries up in India, China or wherever.

Warwick Smith: We have two scale manufacturing plants in the UK, one of which is not functioning at the moment. They do export, but we are living in a global market.

Chair: Interesting though it has been, I am not sure that we are all entirely reassured, but our Government witnesses are yet to come. I thank you, gentlemen, for your time. The transcript of this element of the hearing, and the next, will be on the website in the next couple of days, uncorrected. We will obviously send you a copy of our report, which is now likely to be after the summer recess, I'm afraid, because of timings. You are welcome to stay to hear the Government witnesses if you wish, but I ask you to vacate the table. Thank you.

Examination of witnesses

Witnesses: Sir Chris Wormald, Steve Oldfield, Dr Bruce Warner and Dr Ian Hudson.

Chair: Good afternoon, and welcome back. We resume our hearing on NHS spending on generic medicines in primary care, on the back of an investigation by the National Audit Office into shortages and therefore price hikes towards the end of 2017. We heard from our earlier witnesses that that is not the only time this has happened. The NHS is just one player in what is a global, largely private-sector drugs market.

We are going to get into the main session, but first I shall ask Caroline Flint to ask you, Sir Chris, about something to do with GPs, but I shall introduce the witnesses first. From my left to right, we have Steve Oldfield, the chief commercial officer at the Department of Health and Social Care; Sir Chris Wormald, the permanent secretary at the Department of Health and Social Care; Ian Hudson, the chief executive of the Medicines and Healthcare products Regulatory Agency, which we were hearing about earlier, and Dr Bruce Warner, who is the deputy chief pharmaceutical officer for NHS England. Welcome to you.

Q54 **Caroline Flint:** Sir Chris, there have been some newspaper reports about GPs telling patients that they can only raise one issue when seeing their GP; if they have another matter, they have to organise another appointment. That has happened to two relatives of mine in different parts of England. Are you aware of that?

Sir Chris Wormald: I can't say I particularly was. It would be an issue mainly for NHS England to look at—I am quite pleased to go away and to look into those matters, but it is not one that I have come briefed to talk about.

Q55 **Caroline Flint:** Would it concern you were that practice starting to emerge in primary care?

Sir Chris Wormald: It would be a matter for NHS England, and the—

Caroline Flint: I appreciate that, but would it cause you concern?

Sir Chris Wormald: I am sure the criterion that NHS England would apply is whether there is an effect on patient care, and whether patients are damaged by that. That is how they come at those issues. I suspect they would need to look at the individual policies of those places and conclude whether they had appropriately balanced those patient care questions. My NHS England friend might want to comment, but that is how NHS England come at it. They always come at it on a case-by-case basis rather than generally. I will take the issue away and get you an answer.

Q56 **Chair:** Perhaps, Dr Warner, you will take it back to NHS England as well—unless you feel you have something to add. It is not quite in your purview, I fear.

Dr Warner: Yes, I will take that away and come back to you.

Q57 **Anne Marie Morris:** Sir Chris, we deal with a global market when we deal with generics. I am curious why we are so dependent on generics. We are more dependent in this country than many other countries are. We have heard about how expensive generics are to produce. That is why we are getting them from India and so on. Given where we are going—I am not going to move to Brexit yet—with all our manufacturing and distribution happening in continental Europe, given that we seem to love generics and we use more than anybody else, and given that 81% of drugs used in primary care are generics, isn't there an argument for saying that we should be doing something about trying to manufacture them here?

Sir Chris Wormald: The starting point here is that the fact we have high use of generics is a very good thing, not a bad thing. Generics are considerably cheaper than branded drugs. We are regularly praised in international reports by the OECD and others for our success in generic substitution, which saves us considerable money. We certainly do not see the fact that generics are widely used as any sort of a problem.

Q58 **Anne Marie Morris:** You say they are cheaper, but we have just been hearing about the challenges with prices.

Sir Chris Wormald: Generics—the OECD has reported on this—account for about 84% of the volume of drugs in the UK and 35% of the cost. Branded medicines are the remaining 20% of the volume and 65% of the cost. That shows you the price differential between generics and branded drugs. There are two things here. Generics are almost always considerably cheaper than branded drugs. There is a separate question about whether they are as cheap as they should be in all circumstances, which came out in your pre-panel, but generics are on average massively cheaper.

Q59 **Chair:** There is cheap, there is medium, and there is ridiculously expensive. It is the 1,000% increases that—

Sir Chris Wormald: Yes. We have to distinguish between two things here. The first, which I thought came out quite clearly in your pre-panel, is the state of the overall market, which on average delivers us very cheap

and stable drugs compared with our European colleagues. Indeed, our spend on generics in the year of fluctuations went down, not up. There is then the question—you discussed this with the pre-panel, too—of individual drugs, where you can see very big fluctuations, some of which are not explicable, for the reasons you mentioned, and some of which clearly need regulatory and other action. Our view of this, which will come out throughout the hearing, is that the market as a whole works very well in our favour, but you can see some very strange things in individual drugs. That is one of the reasons we wanted legislation to do the various things that the new legislation does.

Q60 **Chair:** And it is why we are having this hearing. It is those outliers that worry us.

Sir Chris Wormald: And it is why we are having this hearing. But you can have—

Q61 **Anne Marie Morris:** You still haven't told me, Sir Chris, why we don't manufacture more of them here.

Sir Chris Wormald: There are two things there: a lot of the ingredients come from abroad anyway—we have to import, simply because the individual ingredients do not exist here—and manufacturing in the UK is more expensive. You would have more control over your supply, but, just as in pretty much every other manufacturing market on the planet, it can clearly be produced cheaper in other places. So yes, you could have a policy of more domestic supply, but you would still have to import—you would still be locked into the global market, because that is where the ingredients come from—and you would have higher manufacturing costs. The idea that there may be some drugs that you do want to manufacture within the UK is clearly a possibility, but you certainly would not be getting them cheaper by manufacturing them in a high-priced western economy, as opposed to delivering the world market.

Q62 **Anne Marie Morris:** But is not the issue of continuity equally important? We heard from the preliminary panel what happens to patients who do not get these drugs.

Sir Chris Wormald: As I say, I thought your discussion with the panel brought out the balancing act that we do in this very clearly. We both want stability of supply and we want a good price for the taxpayer. We are continuously balancing those things. The concessionary prices is pointed to in the report. The reason we give a concessionary price is because we are worried about supply. We do take very defensive decisions, in that we don't risk patient harm when we set a concessionary price. In terms of whether domestic supply helps you, it was actually NHRA on domestic suppliers that was part of the issue, so it certainly does not prevent those sorts of things. I think there is a second argument about domestic supply, but it doesn't answer the question you raised.

Chair: We can come on to the separate argument.

Q63 **Anne Marie Morris:** Mr Hudson, you must have a better eye than almost

anybody, in terms of the medicines that we buy, because you are licensing the ones that we manufacture here. Tell me if I have this wrong, but I presume that you also have to approve drugs, et cetera, that are coming into the UK, unless it is an EU one and therefore pre-approved. How do you take some sort of overview, to ensure that we get best value for money and security of supply in light of the emerging health trends? You must be as aware of that as anybody.

Dr Hudson: Our role within the agency is to ensure that medicines are of an appropriate standard of quality, safety and efficacy. Our role then is to ensure that products that are sold on the UK market are of appropriate standards, wherever they come from. We will license on behalf of the UK—unless, as you say, some will go through the centralised European procedure—the medicines that companies want to sell in the UK.

Our role is not only in the initial licensing, but through the whole lifecycle of the product, from inspection and manufacturing licenses, through the supply chain and in wholesale dealers as well. We will work with the manufacturers to ensure that they comply, take action if necessary and, if there are problems, work closely with the Department in relation to managing supply issues, such that we can take a risk-based approach to do our upmost to ensure continuity of supply where there is a problem—on a risk basis.

Q64 **Anne Marie Morris:** But it is a very reactive process. Mr Wormald, is it therefore you, within the Department of Health and Social Care, who, given the current predicted state of our health economy, keeps an eye on which drugs we need and which ones we cannot do without, so that the Department of Health and Social Care can ensure that through Dr Hudson's team we are importing, producing and manufacturing what we need, and there is no risk?

Sir Chris Wormald: Not quite. We have the oversight role that you describe, but that is not how we carry it out. This is a free-market system. In terms of what is needed, it is driven by the individual decisions of doctors in prescribing and of NHS England in its policies. What we do is look at the market, take information about where there are shortages, we give concessionary prices where necessary, we have conversations with suppliers and manufacturers where necessary, and we seek to balance the market. We have a market oversight role. What we don't do is—

Q65 **Chair:** When it went badly wrong, did you see that coming?

Sir Chris Wormald: I will be clear about this, because we had identified in advance that there was a weakness in our information gathering and transparency powers, which your previous witnesses picked up on. That was why we had asked Parliament to pass the legislation that it did, to strengthen, perhaps—

Chair: So in short, you did not know that you were going to have this problem.

Sir Chris Wormald: I can tell you exactly what we knew. We began to see price rises in the summer of '17, but at that point we could not tell the cause and therefore what the correct remedies were. Information flows, which at that point were voluntary, not statutory, came in in the autumn. We responded to the original problem through our normal mechanism of concessionary prices and allowing people to raise the price, and that did succeed in the sense that, as I think was reported, we do not have any cases of patient harm that arose from this. I think that is still true, Bruce: we have not identified any. So in that sense the system worked. It was very expensive. Our information flows came in in the autumn—therefore with really quite a delay—and at that point we could identify what the problems were and how they could be remedied. Most of that action was taken by Mr Oldfield, who is really fitted to do this. Then you see the number of concessions go down. So the problem was not that we created patient harm. The problem was that we spent quite a lot of money.

Q66 **Chair:** Yes, that is one of the reasons we are here to discuss it; but there is always the risk of patient harm.

Sir Chris Wormald: This is the point of why we asked Parliament for new powers: we ought in future to be able to use our new information powers to spot those trends and then investigate what is causing them considerably quicker. So can we guarantee that this issue won't arise again? No, but can we say we ought to be able to spot it—

Q67 **Anne Marie Morris:** We have divided this hearing into three areas, and I will get on to the new regulation, but not after this little piece—it is going to be at the end. So I am dying to have a go, because I am not sure I agree that it is the solution to all our problems, but let me leave that.

Sir Chris Wormald: I am not saying it is the solution to all our problems, but I think it is helpful.

Q68 **Anne Marie Morris:** Would you consider this concept of manufacturing here in the UK those products which, absolutely, we need to ensure continuity?

Sir Chris Wormald: I don't think there is any ideology in this. We will consider any solution. However, as I say, the issue here was cost, not patient harm.

Q69 **Chair:** This time. I think Ms Morris is highlighting—quite rightly—that there is a risk.

Sir Chris Wormald: This is the issue I am drawing. If your issue is cost then manufacturing in the UK is not going to help you; it is in fact going to make the situation more difficult, but—

Q70 **Chair:** But Ms Morris is highlighting it is both, isn't it?

Sir Chris Wormald: I can much more see the issue around security of supply when you control that supply but, as I said before, given that you are still reliant on the world market to provide you with the actual ingredients that make the drug, that you happen put the drug together in

the UK does not actually build in a huge amount more security, if the basic ingredient is still coming from India, or China, or wherever.

Q71 **Chair:** We are going to need a lot shorter answers, I am afraid—well, I am not afraid: we will. We have read the Report.

Sir Chris Wormald: Well, I'm sorry, but this is actually a complex market.

Q72 **Chair:** Can we just be clear: the problem was that the system failed for various reasons, and one of the challenges is what grip the NHS, the Department of Health, have on the market.

Sir Chris Wormald: No, I am sorry, but I don't agree.

Q73 **Chair:** It failed in financial terms so it has cost CCGs £250 million at your own estimate, the Department's estimate.

Sir Chris Wormald: No, that is not correct.

Chair: Well, sorry, that is an agreed Report and that is the figure that you have agreed.

Sir Chris Wormald: No. The cost of the drugs on which we gave concessionary prices went up by the amounts that were quoted by the National Audit Office, and we agree with all that. The actual cost of generic drugs to the taxpayer fell in that year by about 4%, so the overall market delivered for the taxpayer about the same volume of generic drugs at a cheaper price in that year.

Q74 **Chair:** So where is the £250 million that is—

Sir Chris Wormald: That is the cost of the concessions that were made on the specific drugs on which we gave concessions. We made a greater saving in the rest of the generic market than we lost in that, which is not to say we do not want to do better on the individual drugs, but the actual cost went down from, I think, about £3.5 billion to about £3.4 billion in that year. This is the distinction I am drawing—

Chair: I am going to ask Robert White, of the NAO, just to clarify, so we can be absolutely clear on these numbers.

Robert White: I think it is fair to say the budgetary pressure was felt most acutely within the local commissioning groups.

Sir Chris Wormald: Yes. Now, the budgetary pressure is the difference between what they forecast and what they had to spend. The total cost to the taxpayer went down by 4%.

Q75 **Chair:** That becomes the nub of it—what they forecast and what they spent, and they couldn't be in control. CCGs individually cannot be in control of these prices. This is where you, Mr Oldfield, at the Department of Health, have a very important role to play to try to mitigate the risks, which is what we are really discussing today.

Mr Oldfield, the price went up. The drugs just about continued thanks to

some clever creative work by pharmacies and GPs, particularly, on the ground; but there was a risk to patients, though it didn't materialise in any patient harm in the end. That risk was still there, and then the cost of these particular drugs went up. It sends out a bit of a signal that the NHS will keep paying for drugs, doesn't it? It has to. How did you use your commercial clout as commercial director to try to ensure that the taxpayer was not being screwed for ridiculously high fees for some of these drugs that we have seen go up enormously in price?

Steve Oldfield: If I may just reiterate—

Chair: If you are reiterating, you can just say you agree with him.

Steve Oldfield: —what Chris said about the system not failing, but succeeding, I want to make it very clear that it did succeed, because we do not have any cases of patient harm and that fine balance between price and supply—

Q76 **Chair:** So the priority for you was patient harm, obviously. But in financial terms, do you feel it succeeded or failed?

Steve Oldfield: In financial terms, it succeeded in the sense that, as an overall generics drug budget or drug cost for the financial year, as Chris has said, the overall cost of the same number of drugs went down by 4%. As an overall system—as has been proven over the long term—the way the market is structured in the UK returns economic value to the taxpayer and ensures that patients get the drugs they need in the vast majority of cases.

Q77 **Chair:** Do you think it is acceptable that some of these drugs went up to the prices they rose to?

Steve Oldfield: That goes back to the conversation that was brought out very clearly by the Professor in the pre-panel. There will always be individual cases that require further scrutiny. I know you want to come on to the data later, but it is true to say that with the new powers in future we will have greater opportunity to delve into those individual cases. I want to reiterate that those are individual cases. The vast majority of the system works well.

Sir Chris Wormald: Just to be clear, we are not disagreeing with you on the individual cases. What we are saying is that we have an overall market, but—

Q78 **Chair:** We get that. You are putting a good spin on what is a challenging problem, and a problem that we are worried is not going to go away overnight, because even though the NHS is a big purchaser, they are only 2% to 3% of the market. Mr Oldfield, are the odds stacked against even the mighty Department of Health and Social Care and the NHS negotiating on those prices, because of the way the system is structured?

Steve Oldfield: No, because the market is structured in such a way that competition drives the prices down.

Q79 **Chair:** In this case, it drove it the other way for some drugs.

Steve Oldfield: No, it did not. It used the mechanism that is in place to allow prices to rise at a time when supply is under threat and therefore patient safety is under threat. You could see it potentially as a safety valve for exactly those cases: as we heard earlier, the vast majority of the problems last year were caused by regulatory interventions because of companies that had various issues with their manufacturing sites no longer being able to produce the drugs.

Q80 **Chair:** We know why it happened.

Steve Oldfield: I think that is brought out in the Report.

Q81 **Anne Marie Morris:** Let's move on to the impacts of Brexit. Dr Hudson, we have talked before about where most of the manufacturing and distribution happens, and you have talked about our need to import most of our generics. Could you give me your view as to what we need to do to put ourselves in a good position to deal with the implications of Brexit, given that we do not yet know what the Brexit deal will be?

Dr Hudson: The Government have outlined their preferred position on Brexit, which is continued collaboration with the European medicines regulatory network, associate membership of the—

Q82 **Anne Marie Morris:** But we do not know whether that will happen; if we assume that that might not happen, what would you do if it did not? We need to know what would happen if there is no deal and no agreement and we do not have the consistency. That is what I am trying to understand. What contingency plans do you have in place?

Dr Hudson: The preferred position is that, but the agency is working on contingency for the different scenarios of a no deal, recognising that the preferred position is that continued collaboration. Indeed, in the Government's announcing their preferred position the criteria were that patients should not be disadvantaged and products should be able to come to market, and indeed the UK should continue to play a leading role in public health globally.

Q83 **Anne Marie Morris:** Those are lovely principles, but what are you going to do?

Dr Hudson: We will ensure that we are as pragmatic as we possibly can be in ensuring that patients get supply, and continue to get supply, of good-quality medicines.

Q84 **Anne Marie Morris:** How are you going to do that?

Dr Hudson: We will work closely with the Department to ensure that the regulation is fit for purpose—but remember that this is a global industry, as we have already established, so we already have mechanisms for importation of drugs from all over the world. We will do our utmost to use the flexibilities that are there in the system to enable regulation—

Q85 **Chair:** Do you have licence to suspend any regulatory powers in order to allow, for example, a manufacturer to continue to manufacture a drug even if there is a concern, to make sure that there is no gap? Can you do that?

Dr Hudson: I'm not sure why we would need to suspend any regulatory powers. We have mechanisms within the regulation that allow us to allow manufacturing to continue.

Chair: That is what I meant.

Dr Hudson: If I look at some of the examples that are quoted as causing some of the problems last year, we will always take a risk-based approach in terms of our regulatory action, weighing up the risk of harm to the supply and risk of harm to patients, versus the risk of not having the product.

Sir Chris Wormald: We may be eliding two issues. There are clearly questions around our exit from the EU about how we do regulation, but of course the vast majority of our drugs, as we just discussed, are not made in the European Union anyway. When we are importing drugs from India and China that does not actually affect it. You have to decide how you are going to do your regulation. The Government have set out their preferred position. We would clearly have to do that ourselves, but where you ultimately get the drugs from is not affected.

The thing that has been debated in the last couple of days, and which Simon Stevens discussed on "Marr" and at the Health Committee yesterday, is the practicals of an awful lot of our drugs coming through Dover. The contingency planning that he described, which the Department is leading, is about that practical bit. It is not the regulatory bit that Dr Hudson was describing. There are those two different themes.

Chair: But both have a role to play.

Q86 **Anne Marie Morris:** What we are saying, Dr Hudson, is that we import a number of our generics, which is what we are talking about today, from India, China and also, clearly, from Europe. What contingency plans have you made to import generics—as that is what we are here today to discuss—from other countries if, for the sake of argument, there are tariffs, it is not affordable, and so we are looking at other markets? What contingency plans have you made for that?

Dr Hudson: We are willing and open to work with the Department or the NHS when they are purchasing drugs. We do not purchase the drugs, but we have a regulatory regime that is permissive in the event of a clinical need. It is proportionate and ensures that patient need is taken into account. We have the regulatory tools to allow us to continue to import drugs if necessary.

Q87 **Anne Marie Morris:** That is very good. Sir Chris, given that you are in charge of making sure that we are still able to get the generics that we need, what plans have you made to think about importing what we need

from other countries outside the EU?

Sir Chris Wormald: As Simon Stevens set out, we are in discussions with our colleagues in the NHS, in the industry and in the rest of Government about appropriate contingencies for disruption of supply. I will not tell you exactly what the plan is for a number of reasons—partly because we are still in those discussions, partly because there is no single answer and partly for various commercial reasons.

It is clear that in any system where you are looking at how you would mitigate a disruption of supply, you would look at some of the issues that you have raised. Where are you importing from and how? What is your level of domestic supply? Crucially, what is your level of buffer stock, and what are the alternative treatments for anything that you are short of? Our plans would involve all those things. I am not going to set out for you today exactly the balance, but that is what we are—

Q88 **Anne Marie Morris:** I appreciate that you are not going to set it all out. Where are you going to get the data from?

Sir Chris Wormald: As you would expect, we collect a lot of data about where drugs are made and which drugs are crucial, and not just for leaving-the-European-Union reasons. We have done more of that, so we have an analysis of what we think we would need. The crucial thing that that shows is that, as I said earlier, there is no one answer. For example, you would look at a completely different solution for a drug or an isotope with a very short shelf-life than for one where you can have a large buffer stock.

That is why there is not one answer. Unfortunately, you have to go drug by drug, and this is what we are doing with our NHS colleagues and others, asking, if there was to be a disruption of supply for any reason—I think it was mentioned in the pre-hearing that there was a disruption of supply because of a strike in a port in India—what is our response? That work is ongoing.

Q89 **Anne Marie Morris:** So you are ready, so that in March 2019 you will have a complete plan for where the drugs we need will come from.

Sir Chris Wormald: Given that it is a market and given the number of uncertainties that you have pointed to, I will not issue any guarantees about what will happen, but we think we will have appropriate—

Q90 **Chair:** Sir Chris, you rightly highlighted that there is a vast difference between those with a long shelf-life and those that would need what you might call "just in time" deliveries. Given what we are discussing with other parts of Government about the border, are you confident that just in time deliveries will still happen, especially if we leave without a deal? You are obviously planning for all scenarios.

Sir Chris Wormald: We are doing our planning not because we expect these things to happen but because, as you would expect, we do contingency planning for all scenarios.

Q91 **Chair:** Are you confident that just in time deliveries will still be possible?

Sir Chris Wormald: I am confident we will have a good contingency plan. As I say, I will not issue guarantees on particular things, for all the uncertainties that I have pointed to.

Q92 **Chair:** So you have a plan. Dr Warner, do you think the Department's plan applies to NHS England, too?

Sir Chris Wormald: We are leading the creation of the plan, but NHS England is completely involved.

Q93 **Chair:** I am sure that Dr Warner is contributing. Are you confident that we can have just in time deliveries, so that pharmacies can get what they need to serve patients?

Dr Warner: Our primary concern is that patients get their supplies and that patient safety is not compromised in any way. We are working with the Department and with colleagues at the NHRA to try to make sure that does not happen in a number of scenarios. As Sir Chris said, that may depend on individual products and situations, but we are confident that things will work in all scenarios.

Q94 **Chair:** We are hearing a lot about scenarios and plans, but practically speaking, how will a drug with a short shelf-life that needs to dribble through at a reasonable pace so that patients get it when they need it, and that is manufactured overseas, get through border controls? How will it get from Europe across the channel or through our ports if we do not have a deal and we are not in the customs union?

Sir Chris Wormald: You will have to look at alternative ways of importing that drug. That is exactly what we are doing.

Q95 **Chair:** So have a special import control system. Mr Oldfield is nodding; perhaps he can give us more detail.

Sir Chris Wormald: As I was saying, I am not going to give the detail for the reasons I gave earlier, but the components—

Q96 **Chair:** Actually, I think patients want to know the detail. If a patient is reliant on a drug, perhaps to prolong their life or keep themselves very well compared with how they would be without it, and there is a risk to its supply, do you not think that patients need to know that you have a workaround? Can you not give us a little more detail? I do not see what commercial confidentiality issues there would be with the EU negotiations in saying that you have a plan to protect patients in case of no deal.

Sir Chris Wormald: As I say, I cannot give you further details, for the reasons that I set out earlier, but the risks you describe are exactly the reasons we are doing the contingency planning.

Q97 **Chair:** Mr Oldfield, can you give any more information?

Steve Oldfield: No.

Chair: You won't now that he has said that. You are the permanent

secretary, Sir Chris; I wouldn't go against you if I was sitting next you.

Sir Chris Wormald: I have set out all I am going to say to you on this issue. I have set out that we are doing the contingency planning that Simon described.

Chair: To be honest, we get a bit weary because we are trying to ask reasonable questions and as a Committee we have a range of views on Brexit—we do not have an ideological position. We just want to know that a plan is in place. You say you have plans and you are aware of the risks.

Sir Chris Wormald: We are aware of the risks and we are doing the contingency planning that you would expect of us. I am not in a position to lay out the exact plan.

Chair: Okay. I am not sure what the risk is of laying out the clear plan.

Sir Chris Wormald: As I say, a number of things are still under discussion and some of them are commercial, so it is for exactly the reasons that I stated earlier.

Chair: You earned your knighthood with that last set of obfuscations, I have to say.

Sir Chris Wormald: I'm sorry, but those are the answers you are going to get, Chair.

Q98 **Anne Marie Morris:** On Brexit, clearly you have the issue about trying to find alternative supplies from other countries, but you also have replicating the supply chain for the manufacturing and distribution of drugs in the UK. Will you look at helping the drug manufacturers and producers based in the UK that currently manufacture and distribute in Europe, so that they will be able to do that here in the UK, quite apart from all the generics we will get from India and China?

Sir Chris Wormald: Just to be clear, we are talking about a transport issue, not a supply issue. We expect to be getting drugs from exactly the same manufacturers as we always have, most of which are not in the European Union. The question is how they get into the country, not where they are made. On the second issue, I don't think we envisage there being any difference about how, as it were, the internal bit of the drugs market within the UK would work under any scenario.

Q99 **Chair:** What about UK exporters to Europe?

Sir Chris Wormald: Sorry; I may have misunderstood the question. Is your question on exporters to Europe?

Q100 **Anne Marie Morris:** How will you help those drug companies that export to Europe from the UK?

Sir Chris Wormald: That would be part of the wider trade discussions with the EU. That is not something that DHSC would do specifically; it would have to be part of the wider discussion. Sorry; I misunderstood the question.

Q101 **Bridget Phillipson:** On the medium to long-term impact of Brexit on pharmaceuticals and life sciences, the UK is obviously a very attractive place where lots of research happens, so what are you doing to mitigate the impact on the sector after Brexit?

Sir Chris Wormald: We are discussing this with the sector, as you would expect. The main actions that the Government are taking are set out in the life sciences strategy that we published as part of the industrial strategy. That is our approach to industry on this issue.

Q102 **Bridget Phillipson:** It is not just about the drugs themselves; it is about our involvement in research and clinical trials and the fact that the UK is a great innovator. We want to keep all that. How can we make sure that we do?

Sir Chris Wormald: That is exactly what the life sciences strategy is about. It covers all the aspects that you have just described. Steve, do you want to say a bit more?

Steve Oldfield: In fact, the discussion around the life sciences strategy is embedded in the new Life Sciences Council, on which sit industry representative bodies, the chief executives of most of the major pharmaceutical companies and Professor Sir John Bell, who is the Government adviser. There is not only a document called the life sciences industrial strategy; there is a forum and there is meaningful discussion about how it will actually happen. You are right: research, in particular, as well as advanced manufacturing, are some of the key elements of that strategy.

Q103 **Bridget Phillipson:** Will we continue to be governed by the clinical trials regulation and by issues around patents? Will that continue post Brexit? Will it be part of the roll-over?

Sir Chris Wormald: Patents is a world system, so it would apply to us—

Q104 **Bridget Phillipson:** But there is a European patents court, isn't there?

Sir Chris Wormald: There is, but the patents system for drugs covers the world market. I don't think that will change. Sorry; this is not my area of expertise. I will check for definite, but I don't think the world patents system will be particularly affected.

Q105 **Bridget Phillipson:** A report I read talked about how, on leaving the European Union, if the UK isn't covered by the unitary patent system, we would be denied access to Europe's patent court, which could result in delays and more costly disputes around patents.

Sir Chris Wormald: I will check that question exactly. It is slightly beyond my knowledge. I will come back to you on that.

Bridget Phillipson: Just returning to some of the issues covered in the Report—

Chair: I think we will briefly go to Ms Flint before we move on.

Q106 **Caroline Flint:** I just want some clarification on the third bullet point of paragraph 3.8 on page 21 of the NAO Report. It says: "governments and insurers in other countries putting downward pressure on the price of generic medicines, resulting in lower returns and manufacturers withdrawing". What prompted Governments and insurers to do that if the market was working and they felt that prices were kept down? Do you know which Governments and insurers that was?

Steve Oldfield: I think particularly the United States market was in a state of significant change at the time. The United States continues to be the world's biggest drug market, so what happens there has an automatic impact on what happens in the rest of the world. The United States has historically been characterised by relatively high generics drug prices and relatively diffuse supply chains. In 2016 we saw a consolidation of supply chains, with retail chains and distribution channels coming together in consolidation, thereby increasing their purchasing power and driving down costs. We also saw Government interventions to say, "We are paying too much for generics and, therefore, we want to pay less." That put in enormous pressure on the generics industry. When the generics industry comes under pressure in the United States, it naturally looks to the rest of the world to see where there potentially may be more—

Caroline Flint: More money to be made.

Steve Oldfield: The differential commercial attractiveness of different markets becomes that much more important, when you cannot just rely on the US providing the vast majority of your—that is what the Report suggests: the pressure.

Q107 **Caroline Flint:** The Report also cites that the margin between wholesalers' buying and selling prices also unexpectedly increased. How do you know that those pharmaceutical companies were not profiteering?

Steve Oldfield: I think that your question was specific to the wholesalers' margins. I do not think we have any concrete evidence that wholesalers' margins were increasing in a way that we could entirely explain. The picture that I would like to paint of what happened last year was already described by Warwick Smith from the BGMA as the perfect storm. The circumstances that came together created a huge amount of turbulence and confusion in the market. Trading, for example, between different parts of the supply chain typically tends to increase when there is turbulence in the market. Much of the turbulence was created initially, or triggered, by the regulatory changes and the fact that two of the major volume suppliers to the UK market—one of which, interestingly, is UK-based, with UK manufacturing—were unfortunately no longer able to produce, because of quality issues at their factory. The market became a much more turbulent place, where prices were going up and down more frequently than they would do under normal steady-state circumstances. It is entirely possible that in that there was a disconnect between different parts of the supply chain.

Sir Chris Wormald: We did change how we did concessionary prices in response to that.

Q108 **Chair:** We are not having that conversation. We need to move on to Ms Phillipson now.

Steve Oldfield: If the direction of your question is what we did about that, I would say that from November last year onwards, when we became aware of the changing relationship between the manufacturers' selling prices, the wholesalers' selling prices and the concessionary prices, we fundamentally changed the methodology by which we collected the data, so that we were no longer reliant on that wholesale bit, which was the bit we understood less, and we went back to the manufacturers' prices and said, "We know more. We have better quality and extent of data from manufacturers, which we can collect in a timelier manner and set prices on the concessions based on those." It was reassuring to see, now looking back with hindsight, that month by month, the concessionary prices came back down in line, not entirely to the pre-crisis level, but in that direction.

Q109 **Bridget Phillipson:** Can you just go back to the beginning? Could you explain to me the mechanism by which you became aware of there being problems within the system? How do you get to know that?

Chair: We need to keep answers a bit shorter please, if you can.

Steve Oldfield: In simple terms, last year CCGs started to report to NHSE that they were seeing pricing pressures on certain lines of generics. In September, NHSE came to the Department and reported that. The Department then started to work actively with all the partners, including the industry associations that were represented at the pre-meeting and other Government bodies and arm's length bodies, to try to understand first, what was going on and secondly, what we could do about it.

Q110 **Bridget Phillipson:** Why was it not until November that there was an analysis of the possible causes of this?

Steve Oldfield: It wasn't that there was not analysis, but we were, to some extent, hostage to the data collection system that was in place at the time, in that the data for scheme M, which is the tariff price-setting mechanism for a large basket of generic prices, is collected quarterly in arrears, if you like. So it wasn't until November, really—well, end of October—that we had absolute insight into how the different parts of the supply chain were contributing to the problem. It was at that point that we had much greater transparency about where the prices were starting from and going to, and at that point we immediately took action. Over a three-day period, I personally met with other members of the Department; I personally met with the five main wholesalers to try to gain some insight. We had meetings or calls with the key generics manufacturers. From that, we were able to derive most of the hypotheses, which are summarised in the NAO Report, and then decide what we were going to do about this.

Q111 **Bridget Phillipson:** We have heard that there was no suggestion of harm

to patients. Could we just hear how clear you are on that and how it is the case, but also about the impact on patients? Obviously, we want to avoid harm, but we also want to avoid distress to patients from having to return to pharmacies, or their carers having to return.

Dr Warner: We have no evidence of patient harm as a result of these price increases, and I think a lot of that is due to the work, which we should acknowledge, of the whole supply chain, including the community pharmacy sector, and their professionalism and diligence in putting patients first and making sure that patients do get their supplies.

I would not say there has been no patient inconvenience. We have already heard that some patients have had to, perhaps, wait a number of days to get their full supply, and pharmacies have had to try different methods to make sure patients do get their supply. But as far as we are aware, no patients have been harmed as a result of that.

Q112 **Bridget Phillipson:** Sunderland's local pharmaceutical committee has been in touch to say that its experience was as you describe. The vast majority of patients were understanding; others were unhappy about not having their full allocation and having to return. Often, unfortunately, the people on the ground who are responsible for providing medication felt the brunt of the frustration about the inconvenience. What will happen that is different next time to prevent this from being repeated?

Dr Warner: I think this will come up when we go on to talk about the Department's new powers. The improved information will give us much more advance warning of this type of thing happening, so that will be different next time. We have always seen supply issues across the sector, particularly within community pharmacy. For as long as I can remember, although it has not been on this scale—absolutely not—we have always seen supply issues of one type or another, and pharmacies have become very adept at managing them and making sure that patients get what they need.

Q113 **Bridget Phillipson:** This is a separate but connected issue. We have seen coverage about the move towards online pharmacies and the impact that could have on UK pharmacies. I wonder what impact you anticipate from the entry of Amazon into the pharmacy market. There has been talk from the Government about moving pharmacies online. How do you think this will impact on the patient experience and on the sector more broadly? I don't know whether that is a question for you or for Sir Chris.

Dr Warner: Well, we already have a mixed model market. As we heard from Mr Burdon of the PSNC, we already have distance selling pharmacies. Amazon are not in the market in the UK at the moment. Who knows whether they will be? It is a commercial sector and people are constantly striving to innovate and produce new models to provide the services that the NHS requires. We are seeing huge steps in innovation in automation, in the use of technology. Simon Stevens has already said on many occasions that we need to embrace those technologies, while making sure that patients have the best experience they can, and of course not all patients want to access services in the same way. Along with that goes

getting best value for the taxpayer. There is a mixed model, and I don't think anybody has suggested that the UK will move entirely to an online market, but it is a part of the sector that is with us already.

Q114 **Bridget Phillipson:** We already know that community pharmacies are facing a squeeze. Some of the work that they do in providing extra support to vulnerable patients will always need to be done. If you are someone who just needs the odd prescription, that's fine; you might want to move to an automated or online system. But what about someone who has significant health needs? How do we make sure, given the pressures that exist in community pharmacies, that those people continue to get that additional support? We have already heard that pharmacies are very good at identifying and responding to that need.

Dr Warner: You are quite right. Pharmacies have come under pressure in the last year or so as part of that drive to get best value for the taxpayer. That mixed model is there to help to cater for different needs in different situations, while that drive for efficiency continues, so—

Q115 **Bridget Phillipson:** Could they be doing more to try to bring pressure to bear on the NHS budget more broadly? When I visit pharmacies, they say they want to do more to help to take pressure off GP services and A&E, yet that appears to be mixed in terms of the direction of travel. What do you think?

Dr Warner: We are about to enter another phase of negotiations with the PSNC, or the Department is, along with NHS England. That will form part of those negotiations.

Q116 **Bridget Phillipson:** Sir Chris, could we make better use of community pharmacies?

Sir Chris Wormald: There is a lot in what you say in all those questions. The number of pharmacies has gone up quite considerably in the last decade—it went up by 15% over 10 years. It has come down by about 2% since our funding changes, so clearly there have been pressures in the last couple of years, but that is part of an overall rise. Will technology affect this market? Yes. As with pretty much any market that involves technology, it is incredibly difficult to predict exactly how, but I suspect that the mixed model that Dr Warner describes is probably the way forward, for some of the reasons that you have mentioned, including people continuing to want the classic community pharmacy. Do we want pharmacies to do more in terms of health prevention and advice? Yes, but of course different bits of the NHS budget—as no one is better aware than the Committee—have to be balanced. That sometimes means tough decisions, as you know.

Q117 **Caroline Flint:** We have all seen media stories of things such as a cream that you can buy over the counter in a chemist for £2 but may cost a couple of hundred quid on prescription. Do you have a hit list, Dr Warner, of those sorts of products that you want to bear down on to stop that being the case?

Dr Warner: We are aware of the media stories around that particular

product. Specials are a whole other arena of the generics market. By definition, they are special. They are bespoke products, quite often, for individual patients who are perhaps allergic to a particular ingredient in a bulk-produced proprietary brand. Individual medicines have to be made for those individual patients. It is quite difficult to talk about specific specials. On the whole, though, the specials market serves patients reasonably well. Over a number of years, we have seen the amount that we spend on specials as a whole go down.

Sir Chris Wormald: It has gone down quite spectacularly. It was £135 million in 2010 and £74 million in 2017.

Caroline Flint: So they are not that special.

Sir Chris Wormald: When we see individual cases, such as the ones we have described, we take them up. The Bill gives us further powers to do that, so—

Chair: We are going to move on to the Bill.

Sir Chris Wormald: Shall I just finish on specials, because it is very similar to the overall story? In the overall market, the numbers look good, but we want to follow up on things about individual products that we are worried about that.

Chair: We will move on to the Bill and the new powers.

Q118 **Anne Marie Morris:** It is always nice to get something helpful, and certainly, the new regulations will help up to a point. As you say, they will mandate the provision of data, but I am concerned, because it says that the producers can provide "reasonable estimates" on sales income and purchase prices, which does not sound like very clear data to me. The provision of routine information on specials is limited to items listed on the drug tariff, which is only about 23% of them, as you well know.

I am more concerned that the mandatory notification of withdrawal of supplies, or possible shortages, which is key to our discussion, is appropriate only when the producer judges that there is likely to be an impact on patients. That is a huge responsibility for any producer, and does not necessarily fill me with a great deal of happiness that you are going to get what you need. Where will you get that data? How will you enforce getting it? How will you fill those holes?

Sir Chris Wormald: As we have described, the new legislation is incredibly welcome. It was much debated at the time. It significantly increases our powers, but it is not the whole answer to those questions. It puts on a statutory basis the information we get from the sector already. It allows us to deep-dive—

Q119 **Anne Marie Morris:** Yes, but that isn't really enough, is it? That is really saying, "All we're doing is making mandatory what we did on a voluntary basis." What are you going to do about it? For a lot of this you get the data only every three months, but you do have additional powers. Are you going to use them? When?

Sir Chris Wormald: Yes, we are. For me, the transparency powers in the Act, as I think your pre-panel said, are probably the most important ones. They do two things. They allow us to cover the entire market, and they mean we get the data considerably quicker. In the particular case we are discussing, we would get it several months—

Q120 **Anne Marie Morris:** Getting data every three months doesn't sound very quick to me.

Sir Chris Wormald: No, it gives us power to deep-dive into particular issues. If the issue that was described in the Report arose again and we began to see price rises in July, we could go and get the data we needed in July rather than wait for the quarterly return in October. It allows us, when we want or need to, to get data out of all parts of the supply chain considerably quicker than our voluntary things.

Q121 **Anne Marie Morris:** Do you have someone in mind to monitor that on a regular basis?

Sir Chris Wormald: To take the case study we have in front of us, when it is escalated to us by NHS England that a problem is being shown up by CCGs, pharmacists and others, we can start analysing that problem basically that day. We can go out and seek the data we need, and hopefully we can be in the position that, as Steve described, we were in at the end of October/early November considerably earlier. Therefore we can take remedial action much quicker.

Q122 **Chair:** It was in September that NHS England came to you with this problem. How quickly, under this new model—

Sir Chris Wormald: If something was escalated to us, we would go out to the market straight away for the data we needed. There would obviously be a bit of a lag, depending on what we were looking at, but it should still be considerably quicker than waiting for the next quarterly voluntary return. That is an absolutely key thing.

Q123 **Anne Marie Morris:** But you're not going to get it any quicker.

Sir Chris Wormald: We should do, yes.

Q124 **Anne Marie Morris:** Why are you going to get it quicker?

Sir Chris Wormald: Because we have powers to go and ask for it when we want it, rather than a voluntary agreement that says we get it quarterly.

Q125 **Anne Marie Morris:** Yes, but what is going to be the trigger to make you go and ask for it?

Sir Chris Wormald: Escalation from NHS England.

Q126 **Anne Marie Morris:** But you already had the link from NHS England, and that didn't change anything.

Sir Chris Wormald: At the moment, we get a piece of escalation and we wait for a voluntary return whenever the next quarter happens to end.

That is incredibly different from getting a piece of escalation and starting to investigate it that day.

Q127 **Anne Marie Morris:** It seems remarkable that you waited. However, I have a concern. This is about data and communication—

Sir Chris Wormald: Sorry, it is not about waiting; it is about when you get the data.

Q128 **Anne Marie Morris:** You could ask for data. After all, it is all voluntary.

Chair: We are talking about the past.

Anne Marie Morris: Anyway, where we are now, you have the mandatory data. It is still only quarterly. You still have to have a trigger. You are telling me that is going to come from NHS England. They have information; you have information. There is an awful lot of data floating around but very little connectivity between it. There is no process to make sure there is a fast track. As far as I can see, there is no real plan as to what you are going to do with it. Perhaps Dr Warner and you, Sir Chris, could give me a rosier picture.

Sir Chris Wormald: Well, I don't agree with any of that.

Q129 **Anne Marie Morris:** Good. Convince me, then.

Sir Chris Wormald: We discuss these issues with NHS England most days. They feed us their information and we discuss what we will do with it. I don't recognise the picture you describe at all.

Q130 **Anne Marie Morris:** So you are telling me that in the Department of Health and Social Care, there is a daily conversation between Dr Warner and yourself, Sir Chris, about information, and you immediately look at it and take action?

Sir Chris Wormald: Not me personally. We have a team within the Department that looks at the drugs market—that is their job, and there are people in NHS England whose job that is. Those two sets of people liaise with each other.

Q131 **Chair:** But Ms Morris has just read out, very helpfully, what the regulations say. A lot of them say things like manufacturers will tell you if they consider there is a harm to patients. These are big judgments that you are asking them to make. You have only had the powers for a couple of days. How will you assure yourself that the trigger is the right one and that they will actually adhere to it? Their judgment on patient harm might not be the same as yours.

Sir Chris Wormald: No, I'm sorry—this is what I'm saying. That is a trigger, but for us probably the more important trigger is the information we get from NHS England about actual prices in the market. When CCGs become concerned about price rises and pressures on their budgets, they report that to NHS England and NHS England escalates it to us. It is not the case that the only trigger is the one set out in the regulations.

Q132 **Anne Marie Morris:** But you are effectively saying that the most important thing for you is what you already get from Dr Warner, yet there seems to be this time delay.

Sir Chris Wormald: No, I'm sorry—we are talking almost entirely at cross purposes. The problem here was not the escalation; it was the ability to go and investigate what was happening in the market.

Q133 **Anne Marie Morris:** What was stopping you?

Sir Chris Wormald: That our powers were voluntary.

Q134 **Anne Marie Morris:** But you don't have to have powers. You can pick up the phone and say, "Please".

Sir Chris Wormald: Yes, and people either answer or they don't.

Q135 **Anne Marie Morris:** But if you don't ask, you don't get.

Sir Chris Wormald: We do ask, but it is very different—

Q136 **Anne Marie Morris:** Did you in this case?

Sir Chris Wormald: Yes.

Q137 **Anne Marie Morris:** And they said, "No."

Sir Chris Wormald: That is the position that Steve described. You get the information that people choose to tell you. That is very different from having a statutory power that gives you a statutory right to that data.

Q138 **Chair:** Ms Morris has rightly highlighted that you rely on a trigger from NHS England. Dr Warner, you went to the Department of Health in September, but you were aware, as figure 4 on page 15 highlights, that prices were beginning to rise noticeably in June, July and August. They had been higher, compared with the previous year, for some time before that.

Was the trigger right for you to know when to trigger the Department of Health? As Ms Morris highlighted, there is a chain, at the end of which is the patient. Are the new rules going to help you trigger quicker to the Department of Health?

Dr Warner: We got our first indication that prices were rising significantly in July. We spent August working with an NHS-funded, not-for-profit organisation called ProScript to try to find out whether there was any substance to the very odd anecdotes we heard in July. We talked to other CCGs and our own directors of finance in the NHS to see whether it was something tangible. That happened in August, and then we escalated to the Department, as Sir Chris said, in September. As soon as we got any inclination that this was happening, we started making our own enquires.

Q139 **Anne Marie Morris:** So, Dr Bruce, how is this new data going to help? Will it make a difference?

Dr Warner: As Sir Chris said, it is probably not going to make a difference to the initial escalation to the Department, but I think it will make a

difference, as Sir Chris outlined, to the speed with which the Department can verify any concerns we have and get solid, comprehensive information from the sector.

Q140 **Anne Marie Morris:** That will have to be seen to be believed. I hope that will be the result. Can I ask you about the things that are not on tariff? Most of the specials and some generics are not on tariff, so none these rules about pricing is relevant.

I know, because I have a mailbag full of cases, that there are patients who have suffered harm because CCGs have told GPs not to prescribe certain drugs. The patient is not told why, they get into a worse heath position and they land in secondary care, which actually costs the NHS more.

What do you propose to do about the things that are not on tariff, where there is no availability of price information or any obligation to choose the cheapest?

Sir Chris Wormald: I will split that in two. I will ask Steve to comment on the commercials and Bruce to comment on the prescribing question.

Steve Oldfield: The new powers contain specific provision regarding the collection of information about special products.

Q141 **Anne Marie Morris:** But only those that are on tariff.

Steve Oldfield: No.

Q142 **Anne Marie Morris:** Yes. It specifically says, "only when they are on tariff."

Chair: Are you quoting from the regulations?

Anne Marie Morris: Yes.

Steve Oldfield: No, the regulations allow us to collect information on the full gamut of specials products.

Q143 **Anne Marie Morris:** The Act does, but the regulations that were only implemented on Monday don't allow you to collect the ones that are off-tariff.

Steve Oldfield: Maybe I need to clarify that for you, then. My understanding was that the regulations allow us to collect information effectively on all parts of the supply chain. In particular, care was taken to ensure we can collect information on specials for that very reason.

Sir Chris Wormald: We will write to you to clarify that. My colleagues say we can collect on anything, but we will write the chapter-and-verse version for you, as you have raised the question.

Q144 **Anne Marie Morris:** That is not my understanding.

Sir Chris Wormald: We will clarify that exact point in writing. Our understanding is that they allow that.

Q145 **Anne Marie Morris:** What about the generics that are not on tariff?

Sir Chris Wormald: Same answer.

Q146 **Anne Marie Morris:** Right. You collect information.

Steve Oldfield: There is no differentiation between types of product.

Q147 **Anne Marie Morris:** Given that there is therefore no price, you can't do anything about ensuring the cheapest product is bought, can you?

Steve Oldfield: We are about to enter into a period of consultation, probably by the back end of the year, on exactly how we implement these powers. The Department will be looking at what kind of options are open to us.

It may be that there are ways of consulting on opening up tenders or asking different manufacturers to quote their best price available for certain types of specials, or it may be that we consider the options for centralised purchasing of specials, for example. At the moment, we probably plan to have the system in place by the middle of next year and we will be consulting on that during the back-end of this year.

Anne Marie Morris: That is a long time to wait.

Q148 **Chair:** How many staff will you need to do this?

Steve Oldfield: There are plans in place with the NPDT.

Q149 **Chair:** What will you do if a company refuses to give you the information?

Steve Oldfield: There are provisions in the powers that specifically state what type of information companies throughout the supply chain have to collect and have to maintain.

Q150 **Chair:** Realistically, what will the sanction be? A sanction in law could take quite a long time to come through. Do you envisage any non-compliance and do you have a plan for that?

Steve Oldfield: That is very difficult to speculate on. Everyone in the supply chain was consulted before the Act was passed and before the regulations were laid.

Q151 **Chair:** So you think that there are powers that are relatively easy to adapt, to provide you with that information?

Sir Chris Wormald: Yes, if people were choosing not to comply with the law, we would take an extremely dim view of that, indeed.

Chair: "Dim view" meaning taking them to court.

Sir Chris Wormald: Ultimately, all relevant action. The law was passed so that people comply with it. It is an important law and we will want to see it properly followed.

Q152 **Anne Marie Morris:** I have one further question. What will you do about this limited power of information collection? It provides for the mandatory

notification of the withdrawal of supply or possible shortages, but only where the producer judges there is likely to be an impact on patients.

Sir Chris Wormald: I will check the exact point. I have not briefed myself on that exact clause. I will write to you on that.

Anne Marie Morris: I am really concerned that that is a huge judgment to be made by somebody.

Q153 **Chair:** Mr Oldfield, do you know that? It is quite important.

Steve Oldfield: No, I think we need to come back to you with the detail. What I would say, however, is that products come and go in the market all the time and the process that you heard outlined in the pre-meeting earlier of constant interaction between the industry, the manufacturing industry, the regulators and the Department, usually is able to pick up most of the cases where there is likely to be an impact other than a simple commercial one.

Sir Chris Wormald: I accept that it is a very important point that you have raised, so we will write you a detailed account of that.

Q154 **Chair:** Dr Warner, obviously we talked about the impact on pharmacists. We touched earlier on the impact on CCGs. Do you recognise that there was a particular impact on them, because it was the primary care level that had to deal with the brunt of the price increases? What has been your connection with that?

Dr Warner: In terms of the concessionary prices?

Chair: Yes, the concessionary prices that went up at the end of last year.

Dr Warner: There certainly was in terms of those medicines that were subject to the concessionary price increases. Having said that, overall, as Sir Chris mentioned early on in the session, we saw an overall fall in the price of generic medicines by about 4% last year. There was an in-year pressure in relation to those particular medicines.

Chair: The point is that when they were forecasting, those particular drugs would be at a lower price and they went higher. That is a pressure on the budget in-year.

Dr Warner: Yes, that is the pressure that the National Audit Office was referring to.

Q155 **Chair:** So have you done anything to provide them with any support? Did you provide any funding to ameliorate the impact of increases?

Dr Warner: Some of that pressure was absorbed by CCGs.

Chair: Which means it will come from other services. Let us be clear; "absorbed" makes it sound nice.

Dr Warner: Some of that would have related to medicines and different schemes that CCGs have around the whole medicines optimisation

agenda, which every CCG is working on, to ensure that medicines are used to their best effect and we get best value from the use of those medicines. That, in itself, generated some offset against those prices.

Chair: That should have been, hopefully, work as normal. They were planning that optimisation anyway.

Dr Warner: They were planning that to an extent. We also saw some medicines, such as Pregabalin, which was a high-volume medicine, come off patent and generic medicines start to come into the market within that year. That happened slightly earlier than was anticipated. That, in itself, generated some unexpected savings, which went to offset those concessionary price increases.

Q156 **Chair:** Really you are expecting CCGs to ride the wave of the market on this. They win some and lose some. You are saying that it balances out.

Sir Chris Wormald: Well, yes. As you know, the vast majority of mandate funding flows down to CCGs and we expect them to manage these pressures and indeed lots of other pressures, across the year, which they are normally successful in doing. Without wishing to pre-empt the National Audit Office's signing off of our accounts, we expect the NHS to be broadly in balance. As I say, there isn't any extra money that is put into the system for these things. We expect CCGs to manage this within their overall—

Q157 **Chair:** The point is that you and Mr Oldfield, the Department of Health, are in a better position to have some control over this. CCGs are quite small. Their overall drug budget is big, but it is not as big as what you are dealing with centrally. Having gone through it this time, what would you do differently, if anything, to support CCGs over this hump?

Sir Chris Wormald: I don't think we would change the financial position, because as I say, the vast majority of mandate money goes to CCGs anyway. In that the information powers we were describing earlier ought to allow us to intervene earlier, that will also allow us to inform CCGs and others earlier and will hopefully mean that we don't get quite such a spike as we saw in this particular case. It ought to allow that.

As I say, none of these things make the issues go away, but they ought to allow all parts of the system to know about that earlier and have a better projection of what will happen going forward.

Steve Oldfield: And in particular the cogency between the manufacturers' selling prices and the concessionary prices that are being set, which ultimately is what causes the pressure on the CCGs. As we saw in the January, February, March period, once we had changed the methodology, that pressure was reduced very significantly for CCGs. With the new powers, that is going to be the new norm.

Q158 **Chair:** A lot of hope is being placed in the new powers, so can I ask each of you briefly to say, from your perspective, what you have learned from this and what you would like to do differently if you are faced with this

situation again, taking into account that you have the new powers? We'll start with Mr Oldfield and work along the panel if that's okay.

Steve Oldfield: I think this has been touched on in the course of the meeting. Clearly, there are always things that one could do better in these circumstances. The new powers will give us the ability, within 48 hours, to collect information where we have specific concerns. That will effectively shortcut the three months that we had to wait last time to get the information.

Q159 **Chair:** You're hanging a lot on the new powers.

Steve Oldfield: Well, they're a very important part of the future—

Q160 **Chair:** Okay. Sir Chris?

Sir Chris Wormald: Mine is roughly the same answer.

Chair: Well, if it's the same, you can agree with him!

Sir Chris Wormald: No, it is with one extra. I think this does demonstrate that the new powers Parliament was kind enough to grant us are the right ones. As this hearing has rightly identified, the challenge now is: how do we implement them properly and get the best out of them? That is the biggest learning from this: the implementation of the new powers we have taken is absolutely vital. We don't want the powers for themselves. It is about all the issues you have been raising about how exactly we use them and whether we use them properly.

Q161 **Chair:** So for you, the thing to learn is how to make sure that the powers are used effectively, that data is properly analysed—

Sir Chris Wormald: Exactly—done swiftly. It is about making sure that the escalation works, that action is taken, that we take the right action against people who are not complying—indeed, all the things you have been raising.

Q162 **Chair:** Are you making sure the institutional memory of what has happened is still in the Department? Happily, it doesn't happen all the time, although it happens with individual drugs.

Sir Chris Wormald: Yes. We have a very nice printed copy of the NAO Report—*[Interruption.]* No, that is a serious point. One of the uses of this, of course, is that it does give you a definitive account of what happened and why that we can refer back to in future.

Q163 **Chair:** Dr Hudson, from a regulatory point of view?

Dr Hudson: From our point of view, it's a case of continuing the work that we do, which is to make sure that companies are in compliance with the regulations, and taking a more and more proactive approach to try to head off any problems at an earlier stage so that these problems get less frequent. But they will happen; manufacturing is a complex process.

Q164 **Chair:** So basically, pre or early inspections to make sure you are warning companies that they might breach a regulation in advance of that.

Dr Hudson: Well, it is continuing a whole range of things: education of companies in terms of the requirements; certainly the inspections; and supporting companies coming back into compliance if there are problems. Clearly, if problems do arise, there has to be a risk-based decision on how we manage that, but we need to do that joined up with the Department of Health and the NHS, thinking about the supply side. So it's very much continuing the work that we have been doing in this area to get more and more proactive to try to reduce the chances of things going wrong, and to act swiftly when they do go wrong.

Q165 **Chair:** That's interesting. At some point, we are going to do another session, I think, on comparing regulators. We might have you along for that, because yours is quite different from other regulatory bodies. Dr Warner?

Dr Warner: As you said at the start, Chair, a lot is being placed on the new powers. The key thing for us is going to be escalating any concerns to the Department as soon as we can, so that those new powers can be acted upon.

It is clearly in our interest and particularly in patients' interests that we get the information as early as we possibly can, so that we can use that to inform advice we are sending out to CCGs. So it's about timeliness of escalation and doing everything we can to facilitate the Department being able to use the powers that they now have.

Q166 **Chair:** Thank you. There is a lot more we could get into about how the global market works and the threats and challenges of that. We have skirted around that a bit today, but we have concerns; I think everyone does. But that is where we are now, and overnight we are not going to change that system—and it's not our job as a Committee to discuss that, anyway.

My final question, Sir Chris, is when you expect to lay your accounts this year, because that's exciting reading for us over the summer.

Sir Chris Wormald: I know. We are in the final stages of discussion with the National Audit Office—I know it's not your bit of the National Audit Office—about our accounts, so we expect to lay them shortly, but the Comptroller and Auditor General has the final—

Q167 **Chair:** Hopefully you will not lay them on the last day before the recess.

Sir Chris Wormald: We aim not to, as you know; we have frequent correspondence on this issue, so I hope to receive no more letters! We anticipate—as long as everything goes right—it being a reasonable amount of time before the date you mention.

Q168 **Chair:** We realise it is not entirely in your hands.

Sir Chris Wormald: It is not entirely in our hands.

Q169 **Chair:** The National Audit Office, quite rightly, are doing their proper due diligence on them.

Sir Chris Wormald: Yes.

Q170 **Chair:** But we look forward to reading them—well, I'm not sure that it's with enthusiasm for what they might be saying, but we obviously have been scrutinising your accounts quite closely for some time.

Sir Chris Wormald: As we expect.

Chair: And this is the year before your cash injection. Anyway, I thank you very much indeed for your time. As I said to the previous panel, the transcript will be up on the website, uncorrected, in the next couple of days, so do have a look at that, and we will obviously send you a copy of the report when we publish it, which is likely to be after the summer recess. Thank you very much indeed.