HOUSE OF LORDS

Public Services Committee

Corrected oral evidence: Homecare medicines services

Wednesday 21 June 2023

4.05 pm

Watch the meeting

Members present: Baroness Morris of Yardley (The Chair); Lord Bach; Lord Carter of Coles; Lord Laming; Lord Porter of Spalding; Lord Prentis of Leeds; Lord Shipley; Baroness Stedman-Scott; Lord Willis of Knaresborough.

Evidence Session No. 3 Heard in Public Questions 24 - 37

Witnesses

I: Sarah Billington, Deputy Director of Medicines Optimisation, Care Quality Commission (CQC); Claire Bryce-Smith, Director of Insight, Intelligence and Inspection, General Pharmaceutical Council (GPhC).

USE OF THE TRANSCRIPT

1. This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Examination of witnesses

Sarah Billington and Claire Bryce-Smith.

Q24 **The Chair:** We now start our second session in our inquiry. I am going to ask our two witnesses to introduce themselves. Ms Billington, perhaps you might introduce yourself and your role first.

Sarah Billington: I am a pharmacist by profession and my current role is deputy director of medicines optimisation at the Care Quality Commission.

Claire Bryce-Smith: I am the director of insights, intelligence and inspection at the General Pharmaceutical Council.

The Chair: Welcome and thank you for coming to speak to us today. We want to try to better understand the regulation of this area of healthcare. We find it quite fragmented, and it is not quite clear who is responsible for what and where it overlaps. Ms Billington, I wonder whether you could start by explaining what regulation there is, who does what and where there is some overlap. It might be a really helpful starting point to get descriptions from each of you.

Sarah Billington: The Care Quality Commission can register organisations that provide what we call a regulated activity. In this particular space, we regulate 10 of the homecare providers. That is because they do a regulated activity.

What does that involve? They do diagnostics; they manage and supply blood products; they do nursing care, which is predominantly the reason why they register with us; they do transport or triage; they provide medical advice remotely; and one of the other significant ones is the treatment of disease, disorder and injury. They undertake activity that is registerable with CQC, and therefore they register with us. They come under our regulatory remit, and we hold them to account for meeting the health and care standards.

Our partner regulator, the GPhC, regulates registered pharmacy premises and the pharmaceutical services delivered from those premises. Claire can describe that in much better detail than I. The MHRA is also regulating in this space because there will be homecare providers who do wholesale or who do some compounding and over-labelling. They may be involved in blood and blood products and they may have medicines and medical devices, which is the remit of the MHRA.

Those are the three regulators that are regulating homecare at the moment. I will stop there so Claire can speak.

Claire Bryce-Smith: Yes, we are the regulator for registered pharmacies across England, Scotland and Wales. In particular, they have to have a retail element to it. So it will be the sale or supply of prescription-only medicines or pharmacy medicines and, as Sarah says, any other pharmacy services that are being delivered from a pharmacy.

In the case of homecare pharmacies, there are 26 of them on our register. As Sarah said, 10 of those are joint-registered with the CQC. We are here to make sure that our standards for registered pharmacies, which is the framework for the safe and effective delivery of pharmacy care, are upheld by those pharmacies.

The Chair: As a supplementary to that, is there a lead regulator? It strikes me that we have some very big organisations in the public sector that are regulated by one regulator. It is very clear and everyone knows who they are. Yet you have a relatively small but very important service here that is regulated and supervised by lots of regulators. It is a mismatch. Is there a lead regulator? As a member of the public, is there one regulator to whom I can make a complaint and they will deal with it on my behalf, even if they have to talk to other regulators?

I have another supplementary to that as well. Why do we not bring them all together under one regulator? That is where my mind was going.

Sarah Billington: Initially you asked whether there was any overlap. Perhaps I can answer in several parts, because there are several parts to your question.

These providers will be regulated by some or all of the regulators in this space, but that does not necessarily mean the regulators are duplicating their efforts. We each look at different aspects of the service. There is no one regulator that could do all of this. As you have heard, it starts with the clinician at the hospital who writes the prescription and who is clinically looking after the patient, and it goes through to the patient receiving their medicines. We are all looking at different aspects of it.

We as the General Pharmaceutical Council probably have a role in all of them because all of them will have an element of the delivery of medicines and the MHRA will do its specialist role. We all have a focus on patients receiving safe and effective care. To the provider there may be occasions where it feels like that we are asking the same questions or we are looking for the same evidence, but we will be doing that on the basis of different pieces of legislation and we will be looking at different aspects of it.

We do collaborate. Claire, I and the MHRA are routinely in contact with each other. We have lines of communication. We share concerning information. We meet routinely to discuss areas. This will not be the only set of services where all of the regulators are involved in regulation. I do not think there are any gaps at the moment because we do communicate well, but there is always room for improvement.

You then asked me about patients. From the patient's perspective, they are patients of the acute trust. They are patients of the hospital. They will have seen their senior consultant at the hospital. They will have received clinical information about their diagnosis and ongoing treatment. These are long-term conditions that they have. They will become experts in their treatment, and it will take place over an extended period of time.

Then there will be a service that comes to their house either with or without a healthcare professional to help them. From the patient's perspective, they will see themselves as patients of the hospital. They should be able to go to their service provider, the homecare service on this particular occasion, with any concerns.

The homecare service will direct them to any of the regulators they are regulated by. On their public websites, it will say that the CQC regulates them, or they are pharmacies and, therefore, will fall to the GPhC. As a patient, it should not be difficult for you to find, via the provider, the regulator to whom you could take your concerns.

When we are doing our regulation, we are always looking for the views of patients. I am not sure whether I got to all of your questions.

The Chair: One of the pieces of evidence we heard last week was that, understandably, patients go back to their clinician, and that just piles more pressure on hospitals. They phone the consultant's secretary or they go back to the doctor to say, 'The medicine's not arrived' or, 'It wasn't what you said I was going to have'. That is a problem.

Sarah Billington: It should be straightforward for people. That is one of the themes that has emerged from all those who are not getting their medicines on time. It is frustrating because they need to be able to complain or raise their concerns in an effective way. They need to be able to get through quickly and get a response from the homecare provider about when it is going to happen, if it has not happened when they expected it to. That is definitely a theme we have come across in our inspection programme. I am sure Claire has come across something similar.

As to which regulator, they would have to go via the provider for them to understand where they could take their concerns. They do come to us directly as well.

Claire Bryce-Smith: I just wanted to answer the one-regulator question as well. Sarah is absolutely right, but I also wanted to add that we have on occasions, including for homecare services, done joint inspections both with the CQC and sometimes with more than one other regulator. Where there may be a problem, we can join those inspections up.

To answer your question simply, yes, there is no one regulator. We all do parts of it, but we also have the ability to come together and do joint inspections, which we have done in the past.

It is the same for the concerns. It probably is quite difficult for members of the public to understand which part to raise concerns to, but the same thing applies. We will pass on concerns that are not for us to either the MHRA or the CQC. To reassure you, as Sarah says, we have regular contact between the inspectorates and with the MHRA.

Sarah Billington: Just to finish your question, I now remember that you asked whether we could bring them all together and have one regulator. I

believe that is not possible under current legislation, and with the expertise and breadth that individual pieces of legislation allow us to have.

We can go to trusts. We have a regulatory remit where a prescription is being generated, where a Service Level Agreement has been agreed or where there are services that are regulated by us. The CQC's expertise is going to be in what happens in a registered pharmacy and the pharmaceutical services. The MHRA has all that expertise about the molecule, the device, the wholesaling and the manufacturing and labelling. There is not one regulator that really has the expertise to scrutinise what is a complicated system. End to end, as we heard in your previous session, the system is not straightforward.

We are not overlapping, but we are all making sure there are no gaps between the work we do.

Claire Bryce-Smith: I just wanted to add to what Sarah said about having one regulator. We cover England, Scotland and Wales as a regulator. The MHRA covers England, Scotland, Wales and Northern Ireland. There would be extra complexities in terms of jurisdiction to consider, if a change were made in one country. That is for the committee to consider further.

The Chair: That is helpful information.

Q25 **Lord Bach:** I probably should formally declare that I have no interests to declare. I want to ask you this. You have heard the criticisms that have been made of the system as it works. Both of you have heard this. What does it take, frankly, to trigger an investigation into a service that some of us may feel is performing as poorly as this one? What more does it take?

Sarah Billington: Do you want to know what triggers the work we do?

Lord Bach: To be blunt about it, why have you not started an investigation into this?

Sarah Billington: Okay. When we bring them into the marketplace, they register with us. That is the point at which we scrutinise what their business plan is going to be and how they are going to function against the health and social care standards. We then register them, and within 12 months we inspect them.

So we are reactive and respond to concerns. Concerns will come to us from the provider themselves. Things will have changed. Concerns will come from local partners, service users themselves, the notifications we receive and information we get from whistleblowers. That would result in us in taking regulatory action or responding.

We also proactively look to engage with trade bodies, including the National Clinical Homecare Association, with patient groups, where we engage with patient groups and you've got the British Society for

Rheumatology I know is very much in this space. We also engage with our stakeholders, including the NHS, partner regulators, the acute trusts and others. So, by our proactive work, we gather information and data that might trigger us to take regulatory action, and we react to the information that comes into us.

When we have had information—I can tell you what we have done with some of the organisations—we have responded. But I would just put a caveat on that: that is for the regulated activities of the 10 that are registered with the CQC.

Lord Bach: I understand that. Has there been any thought about whether you should go further and launch a full investigation into this? I am generalising, but it seems to us that something has clearly gone wrong with this rather expensive system over a period of time, not just in the last six months. Is this not a case where the CQC—and then I am going to ask about the other regulator—should have interfered more actively and more quickly?

Sarah Billington: I sat through the earlier session, and I understand the passion and enthusiasm and the level of scrutiny this group is putting into it.

Lord Bach: It is not passion and enthusiasm. It is just an objective question, really.

Sarah Billington: I come back to the statistic that, on the whole, the vast majority of people receive their medicines in a timely way. The delay in medicines was explained by the earlier group, but it is not just homecare where there are delays in the supply of medicines. There are delays in the supply systems for patients other than homecare patients across the whole of the NHS.

I do not want to take away from the impact on individual patients, though. If individual patients do not get their medicines on time, it can be catastrophic for them. We know they have had to seek further advice, go to A&E and then go back to their clinician. But, on the whole, 98% of the activity of the delivery of medicines to patients in the system is successful.

Would the regulator launch an overarching inquiry based on that? No, but what we have done is look at all of the 10 that are regulated by us and made sure they meet the health and care standards. Where they have not, we have taken regulatory action.

Lord Willis of Knaresborough: Is the information we are getting just nonsense, then?

Sarah Billington: No, it is not. These patients have a voice, and that is great. They have a collective voice by which they have been able to raise the concerns they are individually feeling about homecare services. They are experts in their treatment because they are part of designated chronic disease groups.

Equally, there will be patients outside the homecare service who are also experiencing difficulty in getting hold of drugs because there are delays in the supply chain across the board. My colleague from the RPS alluded to the difficulties there are within the supply chain at the moment and the issues with pricing. I think you raised the issue about the contractual arrangements for reimbursing the people supplying medicines and the impact those have.

I am not taking away from the individual impact on patients, because we know that is significant. But as a regulator we look at a system. Is the system functioning generally well? Within that system, are the individual providers meeting the Health and Social Care Act standards? Where they are not, we will take action with the individual providers.

Lord Bach: This is the Quality Care Commission. Do you do not think you have an obligation in this particular case?

Sarah Billington: We do have an obligation. We discharge our regulatory function with each of the individual providers. I am sorry if I misunderstood your question. I felt the question was asking whether we were going to do a thematic review or an overarching review specifically on homecare.

Lord Bach: That was my question.

Sarah Billington: We are regulating individual providers and we are holding them to account. We do require them to meet the standards and we take action where they do not. Would we do an overarching or thematic review against the backdrop of the health and social care landscape? I am sure my colleague can provide a written answer, but I do not believe it is something we would be doing a thematic review on at this moment.

Lord Bach: Claire, could I ask you to answer that question in your capacity as a regulator, given all you have heard about our concerns?

Claire Bryce-Smith: Absolutely. Very similarly to what Sarah says, we register individual pharmacies. For each of the 26 pharmacies that provide homecare services, we have controls in place at registration that give us confidence and assurance as to whether our standards will be met every day. We similarly do a reinspection or full inspection at six months. That is part of our way of ensuring that, when they are up and running fully, our standards will be met and therefore safe and effective pharmacy care will be delivered.

We then do routine inspections as well as intelligence-led inspections. Out of the 26, almost all of them have had at least one routine inspection. That is a way of making sure we understand what is going on and how well those standards are being met. When we receive concerns either from another regulator or from individual patients or stakeholder groups, we look into all of those and take proportionate action.

At one point around 2020, we did have quite a few concerns around one of the homecare providers. That resulted in an inspection, which resulted in an improvement action plan. All of those improvements were put in place. We recently inspected that one in 2022 and we were happy and satisfied that those improvements had been sustained.

A bit like Sarah, I would say that only two out of the 26 homecare providers did not meet our standards. Both of those had improvement action plans and were then improved. So overall, in terms of the risk profile, they are not necessarily as high a risk as some of the other community pharmacy setups we are looking at, such as online pharmacy, which does not perform anywhere near the same.

That does not mean this is not an issue for those individual patients. That is why every single time we get an individual referral it is followed up with the homecare provider. We make sure and track that improvements are being made. If there were problems, we make sure lessons have been learned, problems have been rectified and risks are being managed.

Lord Bach: Is this system working well on the whole, then?

Claire Bryce-Smith: From the evidence that we get from inspection, from our perspective, it is a model that is performing quite well overall. There are only a few that have not performed well. So yes is the answer to that. We have other models of service provision that are not performing anywhere near this level.

Q26 **Lord Porter of Spalding:** If only 2% of patients are getting a bad service, do you monitor the level of that bad service? Do you know how many of those patients have been affected to a level where their conditions have been irreparably made worse or they have then become a burden for direct, proper medical care in hospitals? Is that number in the 2%?

We certainly got the flavour last time that this is a massive problem. If you are saying that it is not a massive problem in terms of numbers but it is a problem for the people who experience it, do you grade the level of experience they have? Do you have any data showing that, out of the 2%, 1% died, God forbid, because they got a bad service and the other 1% had their life-changing conditions made so bad it ruined the rest of their life? Do you have that sort of data as well?

Sarah Billington: I am afraid we do not collect that data. I am not sure anybody does. When we go into the services registered with us, where we know that one of the themes of why they are perhaps not performing as well as they could was delayed or failed delivery, we have taken action about what they have done to identify that failed delivery and what have they put in place. In one of them, we insisted on having a senior clinician contact each of those patients to discuss their care and to discuss whatever needs to be done to assist those patients.

In terms of collecting data, no, we do not collect that data. I am not sure Claire would be in a position to answer that either.

Claire Bryce-Smith: That is right. We do not collect that data either.

Q27 **Lord Prentis of Leeds:** If I could go back to the model that a number of people have spoken about, your assessment was that the service is meeting the model. When you look a little bit more deeply into it, there are question marks. If the model enables a prescription to remain in the hospital for 14 days, it does not seem to me like that model is providing a good service.

It may well be that you are meeting the 14 days, but the issue is being handled through post on paper. I have made this point before. An NHS patient with the NHS app going to a doctor or even phoning a doctor can have the prescription emailed through on the app. If you tick a box, it goes through to the chemist. The chemist might be willing to deliver or the person can go and collect it. That can be done within minutes, if it is urgent.

Sarah Billington: You have raised a very interesting point. I heard it in the earlier session. It is quite good to have an opportunity to unpick that a little bit.

First of all, these patients are not acute patients. They are chronic patients. These patients have long-term conditions. Unlike the very rapid response you might need if you had an infection and you needed a prescription for an antibiotic, this is not the case with these patients. This is planned care. I understand it is frustrating to hear that perhaps a prescription takes a period of time to get from the clinician who is writing it to be handed over to the homecare system.

In some ways, that is a little bit of a distraction, because how long it takes should not impact as long as the system moves according to the dates everybody has agreed to. It is when there are delays in the prescription getting through. If it was always declared that it would take 14 days, you can plan ahead because none of this involves the acute delivery of medicines.

One of the reasons why it takes so long is that it is not like your GP writing a prescription. They have the huge advantage of being able to send their prescription—most are now electronic—to the community pharmacy. It is the community pharmacy that undertakes the clinical check of that prescription before then deciding to dispense it and it going on to the patient. If there is an issue with that prescription, it goes back to the GP. It is the pharmacist's job to have that clinical oversight.

You heard from the previous session that the senior consultant in the acute setting writes the prescription, but then it goes internally to their homecare team for them to make that clinical check. As you heard from colleagues earlier, those homecare teams are small. They are often under tremendous pressure. There will be huge numbers going through. Making that clinical check is clearly taking longer than it does when your GP and your community pharmacy are working on it together.

I totally agree with you that there is an issue with not having a streamlined process to get the prescription to the homecare provider and using the post instead, with all the problems that are associated with that. The communication between the trust and the homecare provider is a great opportunity to improve that end-to-end process. But it is never going to be instant.

It is a bit like the situation where you have a chronic condition in the primary care setting and you engage a pharmacy to do your repeat prescribing. That often takes a number of working days. You are putting in your request with your slip, getting the prescription and then it is sent electronically. We have been able to do a lot in the primary care setting to streamline and improve that, but, of course, each of those trusts are individual organisations. They will have different infrastructure and different IT systems; they are not interoperable.

I understand, but the 14 days is not the issue. If it takes 14 days, you can factor that into a logistical plan. The issue is when it takes longer, when it is not meeting the targets, when the drug is not available or when it is not possible to make the delivery on the day the patient wants it.

The Chair: I can see the rationale of that. Logically, that is absolutely right. The more different jigsaw pieces there are, the more chance there is of something going wrong because every jigsaw piece can go wrong. Although it takes 14 days, it is very difficult in this day and age, when you think about what we are doing with community prescriptions, when we go to the GP. Why is it still a written prescription in the post? We could make a long list between us of things that could go wrong, so that it will not be 10, 12 or 18 days; it will be longer.

So, while you are logically right, why do we have that system? Why do we not have something much more straightforward? Is this a question for Claire?

Claire Bryce-Smith: I agree with what Sarah has said. I just wanted to share that, through the inspections we have done of homecare services, there is no doubt that there is a common challenge, which we look at as part of how the pharmacy manages that risk, which is the paper-based system. That is not true for all of them.

Some of them do have electronic prescriptions, but there is quite a high proportion of paper-based prescriptions coming into the actual pharmacy, which means they need to be scanned in. As somebody else said, it is very much another handover point where there is an opportunity for delays to occur and mistakes to be made.

I understand that there is work going on between various homecare providers and trusts to look at the templates. There are often different paper templates that they come in. It is all about how that is transferred on to a system. There is no doubt that this is a challenge for the system.

From our perspective, once the pharmacy has it, we are looking at their processes and procedures, but it is a challenge when you are looking at the whole system, which others have picked upon. As Sarah said, there can also be stock shortages. Even in community pharmacy, they cause re-work and delays because people have to alter how much medicines people can get at a particular time.

Q28 **Lord Carter:** Is 10 days enough, then? The previous witnesses made it a major point. I am a bit confused. Can you help me out? Should it be 20? Then we would have no problem.

Sarah Billington: The average is 14 days.

Lord Carter: We cannot return to the previous witnesses, but perhaps you can help us. Is that enough? In other words, is the flow of these drugs to patients being adversely affected? We have heard about paper. We know all that. Would extending the time be reasonable? Are we just being optimistic about the system, given that we do not have enough staff, the Post Office is not working, Christmas is coming?

Sarah Billington: I would go back to the 98%. The prescription element of it is very frustrating. People look at that and say, 'Why does it take so long for something to happen when it could take less time?' I am not sure that is the causative factor for the 1.8% who do not get it on time.

The failure to get the prescription to the homecare team in a timely way will be one of the factors. But the homecare team and the trust teams are under tremendous pressure, and they are putting huge amounts of effort and human beings into getting patients their drugs on time. You could simplify it and accept a more streamlined process, whether that took 10 or 14 days. If everybody knew it would take that amount of time to get the prescription to the homecare service, if when it got there it was effective, came in a format they could use and they did not have to return to question any part of it, everyone would be putting fewer resources into the process and more resources into the bits they have control over and could do better at.

Lord Carter: We quite accept your very well made point about the prescription time. I am just curious, though, about whether people are reacting to knowing these things and amending their processes, given the fact we are using paper. That is all.

Sarah Billington: I would not be able to answer that. If they could do it electronically, it would save them a lot of time.

Claire Bryce-Smith: Our understanding is that the ones we have inspected have built that into their processes. Part of what we look at is the risks they manage. Exactly as Sarah says, when it comes into the pharmacy, whether it is a community pharmacy or a homecare services pharmacy, they have to make a clinical check. If they are not quite sure whether the medicine is appropriate, they will go back to the hospital to check that out. To a certain extent, they do build in that time. It is when it goes over that time.

Lord Carter: How many thematic reviews has the CQC undertaken in the last three years?

Sarah Billington: I am afraid I do not know the answer to that. We are very happy to write you, but that is not a question I can answer at this moment.

Q29 **Lord Willis of Knaresborough:** You were observing the last session so it is fair to ask you this. One of the issues that was raised really quite powerfully was this business of the interoperability between community pharmacies and, in fact, the main programme of electronic prescribing we are talking about in terms of homecare services. Do you see any problem with that? As a regulator, ought you to be taking a lead on this rather than simply waiting for it to carry on?

Sarah Billington: Over a period of time, trusts have built up their own internal digital systems as individual businesses. It is NHS England that makes a decision as to who will be able to access what we call electronic prescribing.

Lord Willis of Knaresborough: I am not debating that. I know that. Unless NHS England gets evidence from a quality regulator that says, 'This matter needs dealing with', they will not do it because they have other things on their priority list. Is it not a priority to merge these two really important services?

Sarah Billington: I understand what you are saying and I can see that it is frustrating, but I have to say that CQC can only act within its regulatory remit. We can only hold providers to whether they meet the health and care standards. They could perhaps do that with the interoperable systems you have heard described, but that does not mean they are not meeting the health and care standards.

For each of the ones that are regulated by us, we will say, 'Do you meet the standard?' If they do, in whatever way they wish to—we are not prescriptive on how they do that—both at the trust level and at the homecare provider level, they are still meeting the healthcare standards and we have no remit to go further than that.

Lord Willis of Knaresborough: Claire, would you like to respond to that as well? Do you see that problem?

Claire Bryce-Smith: As I said before, when we have done inspections, the vast majority have met our standards. In answer to your question, we do look across but, like Sarah, we look at individual pharmacies. We do not have jurisdiction to look at a whole system within a geographical area.

Having said that, we use our insights from inspections to see whether there are particular problems that come up. If we inspected 20 healthcare care services in terms of pharmacy provision and they all came up with the same issues, we probably would raise those, as we have done with other types of service models.

However, both Sarah and I have said that, from our own regulatory activities, for whatever reason—it may be because the individual providers are working around all of these issues and not doing a bad job at all—it is not something that has risen right up the list for us to start doing something about or talking to DHSC or other people as well.

Q30 **Lord Laming:** We are interested in how you assess risk in this field. As you heard in the previous session, if there is one thing that came through to us, it is that there is no system of accountability at all. Nobody is responsible for ensuring the service works. The Care Quality Commission states—I am not nitpicking, but words matter in this business; people's lives hang on this—'We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care'.

I do not know quite how you can say that in this field because, as I say, we have just heard about what I thought was a really rather unsatisfactory position. When you inspected one of these organisations a couple of years ago, you discovered that there were 9,805 patients whose medicine was missed or delayed. We find it difficult to know how you assess risk.

Sarah Billington: Would you like me to explain what we do when we receive concerning information and how we use our powers?

Lord Laming: Yes. It is all right when you receive information. That is a bit late. The damage has already been done to these people. You say, 'We make sure that health and social care provides people with safe, effective, compassionate, high-quality care'. Speaking personally, I do not understand how you can make that claim.

Sarah Billington: We regulate for the Health and Social Care Act. Everybody is registered with us. We hold them to account as to whether they have met the requirements of the Health and Social Care Act. Where they do not, we take regulatory action. There are going to be times when we receive information that they are not meeting the standards. At that point, we use our structured decision-making to decide what the risk is and what we are going to do about that information.

Let me explain the decision tree and the powers that we have. We use what we call a management review meeting when we become aware of concerns. When a whistleblower or a patient raises a concern, they come to us to say, 'The service I am receiving from this provider is not adequate'. We will make a decision on what we are going to do. Our lawyers will be present at that meeting; experienced inspectors will be present; experts in that particular field will be present. We use our decision tree because we need to be consistent in what we do.

We can take a number of actions. I have to say that one of them is that we will do nothing with that concerning information because it is outside our regulatory remit. We would pass that concerning information to our partner regulators if we felt it was within their regulatory remit.

Having established that there is something for us to do, we will then use our regulatory powers. That could be going to see a provider, in other words crossing the threshold; it can be looking at the data we have; it can be a discussion with the provider; we can place requirement notices on providers saying that they must do certain things, which we have done; we can issue warning notices; or we can place conditions on their services, which can range from not being able to take any more patients or having to speak to us and provide us with audits of their work on a weekly basis.

There is a scale of activity that we can take. I can give you the example of Lloyds. Lloyds is one of the ones that is regulated by us. We inspected them in 2021. At that time we discovered that they were inadequate so we issued them with a warning. We got the concerning information in; we went to the provider; we undertook an inspection; and we found them to be not meeting the healthcare standards. We then issued a warning notice against regulation 18, which is about complaints—that will definitely be something that is a theme across these services—and 17, which is governance. I know governance is something of great interest to you.

We required them to make immediate improvements. The service was placed in special measures. They were under particular scrutiny. They undertook the work. We discussed on a regular basis with them how that improvement was going. We reinspected them a year later in 2022. They were rated 'good' across all five domains. We have seen a service that is not doing well, but we have brought it up to standard. On inspection, it is doing well.

That is just an example of how we have worked. There will always be services that are not necessarily doing well, but part of regulation is to identify those and then to take the appropriate action.

Lord Laming: That is very helpful, but we have received evidence from users of these services, patients, who say they feel like they have been let down, that there is nobody they can turn to and that nobody is going to sort out the system and deal with their frustrations, their disappointments and their vulnerability.

Sarah Billington: If they come to us, we will definitely listen to their concerns and we will definitely act on what they have told us. During inspections, we also contact patients, even if they are home-based, to get their views while we are doing the inspection process so we better understand how patients feel.

It can only be a snapshot. Regulation can only be a dip test of patients because they will have so many. Some have thousands of patients. We have definitely sought their views. I am sorry to all those patients who are frustrated by not having someone to take their views.

At the moment we have a programme called 'Give feedback on care'. We are actively encouraging people to come to us and we are promoting that

across social media. I am very glad that some of these patients have patient representative groups that are definitely helping them and drawing together their voices, which puts so much more power behind it.

Lord Laming: I just have one more question, if I may, Chair. Is your evidence to the committee that the system is working well?

Sarah Billington: This is not me trying not to answer your question, but I do have to be factual. We need to remember that a lot of the issues—this is not passing the buck—will be about the delivery of medicines, which does not fall to CQC.

The evidence I can give the committee is that, for the 10 services we regulate and register, the system is working well. Our regulation of them demonstrates that. Where they are not doing well, we are using our regulatory powers adequately and effectively. We are seeing improvement and we are driving improvement.

But we are not complacent. It is very good that this focus has come, and there is a lot for us to take away from this focus. You have talked about thematic reviews. There is something for us to go back and discuss. 'What do we need to do? Is there more we could be doing in this space?'

Q31 **The Chair:** You sent us some data on the number of times the organisation takes action following inspection. Is it possible to send us some data just as it applies to homecare medicines? Can you tell us how many complaints there are in this area? It is good to have the general information, but it is not as helpful for this particular inquiry.

Sarah Billington: Yes, we can do that. We can provide you with data on the 10 we have, what we have done with each of them, when we have done it, what interaction we had with patients and what regulatory powers we used. I am sure we can obtain some data on the specific whistleblowers or specific complaints coming from individuals.

As I say, we work closely with the National Clinical Homecare Association and patient representative groups like the British Society for Rheumatology. We sometimes get information from them. That will not be in the data we have about complaints because this is part of our proactive monitoring.

The Chair: We are trying to work out, given the amount of evidence we have that things are not good, how many times you take firm action and something changes as a result.

Sarah Billington: We can definitely do that. We will send that to you in written form, if that is okay.

The Chair: There is something I still have not quite grasped. You have said 'the 10 that you register'. You mentioned it twice in the comment you have just made. Did you say that the things you do not register were things like transport? Let me ask a simple question. What else is there apart from the 10 you register?

Sarah Billington: There are providers of homecare services that are not registered with CQC because they do not do a regulated activity. As Claire said, there are 26 of them. They all have a pharmacy element to them because they are all supplying medicines.

The Chair: I understand that now.

Sarah Billington: Only 10 of them have the nursing part, treat disease, do diagnostics or provide remote advice. That is what has triggered them to be regulated by us.

We do regulate all of the trusts that are contracting services. We are speaking to chief pharmacists; we have an ongoing conversation. Part of that conversation will be about the service level agreements they have for a number of things, including homecare services and how they are assuring themselves that patients are receiving medicines in a timely way. Ultimately, they are patients of the trust.

Q32 **Lord Prentis of Leeds:** Can I just be clear about something? The regulation does not include delivery.

Sarah Billington: The CQC does not regulate delivery. That is covered by the General Pharmaceutical Council because that is a pharmaceutical service. We do not regulate community pharmacies or any of the pharmaceutical services delivered from community pharmacies.

At the beginning I was saying that we butt up against the other regulators. They do not regulate anything that happens in a trust or anything that happens in nursing care, but the delivery of medicines is regulated by the General Pharmaceutical Council.

Lord Prentis of Leeds: You do not see a need to bring them together.

Sarah Billington: They are brought together in the collaborative working that we have. There are different pieces of legislation, quite understandably, which impact infinitely more than just homecare services. There is human medicines legislation; there is legislation about what happens in a community pharmacy and what happens to prescriptions. Again, who can handle medicines? Who can make clinical decisions?

One regulator will not work in the current system because you would have to change so much legislation. In changing that legislation, the unintended consequences would be catastrophic for the other parts of the system. You need us all to work collaboratively together. Where our regulation ends, we hand that information to the General Pharmaceutical Council, which we do on a regular basis. The flow of information between our two organisations is ongoing and effective.

Lord Willis of Knaresborough: Since 2014 we have been looking at bringing the regulators together. You are saying it is all a waste of time.

Sarah Billington: No, not at all. I am saying that we are together as in working together, not as in giving it all to one regulator.

The Chair: You have to have someone in charge. There is another model. Take Ofsted inspection of early years. I may get this a little bit wrong. They are an education inspector and they found themselves having to inspect social care to ensure the well-being of little children. They did not have the skillset. Not all inspectors have the skillset. They bring people in to do that, but there is absolutely no question who is in charge. Everyone knows Ofsted is in charge.

I absolutely take your point about the different skills, but our problem is that we cannot see a structure, other than sending each other emails to say, 'We have picked up a problem down there', that brings the regulators together.

Lord Willis of Knaresborough: Well done, Chair.

Lord Carter: Chair, can we establish who holds the ring? Is it somebody in NHS England?

Q33 **Lord Shipley:** To me, this is the central issue. There is the regulatory environment, and the answer has been that people collaborate and so on. I want to go back to a previous witness, who I think you heard in the first session, who said that no one has oversight. I would like to know who has oversight of the system. Does anybody have oversight of the system? If so, could you tell us who it is?

The Chair: Who is the boss? Who is in charge of all these many regulators who have bits of the cake?

Sarah Billington: No small questions, then. This is how I would view it. Ultimately, these are patients of an acute trust. Whether the patient is receiving the right clinical care and the right medicines is the responsibility of the acute trust. Within a trust, it is current practice that this lies with the pharmacy department. Ultimately, the person in charge of the pharmacy department is the chief pharmacist, which is a statutory role. Every trust has to have a chief pharmacist.

Trusts themselves are not joined up. The NHS is a lot of organisations independently busily going about their business and delivering to their localities, but they are not one cohesive group. If you were to ask me, 'Who is overarchingly responsible for what happens to these chronically ill patients who receive specialist medicines and how they receive it?' it would lie with NHS England. They would be responsible in deciding the strategy.

The strategy is that we want patients to receive treatment in their own home, which is fantastically advantageous to patients. They love it. They love to be in their own home and receive medicines. It is great for the NHS because they are not going in and out of the hospital in order to make further trips, be present or engage with the pharmacy department in the hospitals, which are under tremendous pressure.

Ultimately, what happens to this whole system is dependent on what NHS England wants to do. They are the commissioners; ultimately, they are the purchasers; and they are the ones who decide clinically what happens to that patient.

Along the way, they have involved lots of organisations. As our colleagues from the previous session said, they are in the private sector. Lots of parts of the NHS are in the private sector, contracting their services. Again, unless it is NHS England making strategic decisions, there is no one saying overarchingly, 'This provider is not doing this and this'. The National Clinical Homecare Association does a very good job of crossing the boundaries and keeping some sort of cohesive oversight of what is happening with the NHS, the regulators and the providers.

I cannot name a particular person in NHS England. There is a chief pharmacist. He may be a person you might wish to speak to. In terms of that overarching view, it is not just pharmacy services that are involved in this. Patients will be receiving nursing care and other healthcare professionals will be interacting with them. Ultimately, the person making the prescription is going to be a clinician of a particular specialty.

I do not know whether Claire wants to come in here.

The Chair: I was going to invite Claire to come in because we never gave her a chance to say whether she was happy with the way things are. Perhaps you could backtrack a bit and answer that one.

Claire Bryce-Smith: Am I happy with the way risk is assessed? What was the question?

The Chair: We got waylaid before asking you whether you thought the system was going well. If we can go back to that point, we can take it from there.

Claire Bryce-Smith: Sarah put it very eloquently. From our perspective at the GPhC, we only look at the registered pharmacy part of this. We do not have a view or a jurisdiction over the whole system. We are not in a position to be able to give any comment on who should be doing what. We are just looking at the individual pharmacy. As I have said before, we are not looking at the whole system, but we are looking at how those individuals perform. Our inspection evidence tells us that they are performing quite well against our standards.

Lord Laming: Chairman, it has been put to us that, if somebody writes to NHS England with their complaint, they will be referred to the trust. If they write to the trust, they will be referred to the local hospital, the pharmacist, the GP or whoever it may be. In other words, they get passed from one person to another all the time. If they write to the regulators, they are incorporated into this loop. There is no accountability in the system. You cannot say to a patient, 'If this is not working for you, this is the person to whom you go'.

Sarah Billington: If they do come to us, we do act on all of the information we have. I do hope patients have not contacted CQC and been rebuffed or told to go elsewhere. I would be disappointed if there were any information you have on that. We expect patients to be able to come to us, and we will look at that information and respond to it. As I say, sometimes we need to pass it on to another regulator.

I agree with you. It is difficult for patients to navigate their way through what we all know is a complicated system. I have great sympathy for them.

Lord Shipley: The answer I have taken from this is that there is no named person and that it is NHS England, with all that represents. I share Lord Laming's concern. If you do not have a single overarching body or a single named person, it gets very difficult to understand where responsibility lies, who has oversight of the structure and how it works.

This is something we might want to pursue in a further inquiry, because we will have the chief pharmacist with us and so on. It may be wise to await those discussions, but I find it very helpful at least. What you have both said has been illuminating.

Sarah Billington: Homecare is a sector that is set to grow because it is so welcomed by patients, but it is just one of a number of strategies that will also be seeing the delivery of drugs and healthcare in patients' homes, such as virtual wards. It is really good to highlight issues now and perhaps work together on improvements, because the complexity is just going to grow. Virtual wards will be dealing with acute patients. It is the direction of travel. Shining a light on this now is very helpful.

Q34 **The Chair:** We may very well come back to you about complaints against the CQC. We think we have some evidence.

There is one more thing I want to take up. All this seems to depend on these written standards. The approach to regulation seems to be that, if you think they reach your standards, that is all right. Members of the public do not get to see how many of those standards they have met and whether they are the crucial ones.

Sarah Billington: We do publish all of our reports and they are available to people and they can see exactly—

The Chair: So the data is there.

Sarah Billington: Yes, absolutely.

The Chair: I have not looked at the standards so I am just floating this. Are they absolute standards? There are lots of sets of standards. Is it 'working towards', 'have an ambition to' or 'trying their best to achieve'? Most of them could pass that. It could also be 'absolutely will do', 'without exception achieve' or 'wholeheartedly drive themselves towards'. On that spectrum, where do your standards lie? It seems to me that what is in those standards is absolutely key. If they are soft, nothing else works.

Sarah Billington: I am going to slightly disappoint you, in so much as we all have different standards. For them to be regulated by the Care Quality Commission, they have to meet the health and care standards. Those are not soft standards. Those are absolutes. They must meet those standards. If they are not meeting those standards, we will be expecting them to improve, and we will be using our regulatory powers to ensure they do improve. The 10 regulated by us will have to meet the health and care standards.

Those regulated by the General Pharmaceutical Council will have a different set of standards. They are not going to be radically different, but they are different.

The Chair: It is a different activity.

Sarah Billington: Yes, it is a different activity. If you are referring to the standards that the individual providers have set as a trade standard or a sector standard, those are not regulated by either the GPhC or the CQC. Those will be what they have to do to meet their KPIs. That is probably more commercial within each provider, if you are talking about the standards that were referred to by the lady who came before.

Yes, the CQC will have a set of standards and the GPhC will have a set of standards, because we are looking at different things. We do not have the MHRA here, but they will be looking at different things when it comes to manufacturing and wholesaling.

Claire Bryce-Smith: Chair, can I just come in? We have 26 standards that apply to registered pharmacies. This may or may not give you assurance, but we run a system in which to meet our standards they have to meet all of the standards. They cannot meet 25 of them and they cannot meet 20 of them. They have to meet all 26 in order to meet our standards.

Just like Sarah said, our reports are all available for the public. Where they do not meet our standards, even if it is a single standard, that automatically triggers an improvement action plan. That is also available to the public, so they know what we have found that has not met our standards, what improvements are being made and importantly by when and, if necessary, whether we can take stronger legal enforcement action.

Q35 **Lord Carter:** Do people in your roles go to international conferences?

Sarah Billington: I would love to go to international conferences.

Lord Carter: You should look at the committee's recommendations.

Sarah Billington: Now you have mentioned it, it will definitely be on my list. I sadly think they will all be done remotely, but the answer is no. We are asked to give our expertise to a variety of providers and sectors. We do a lot of work with many providers on how they can meet the standards and be better. We signpost them in that way.

Lord Carter: To both of you, we had evidence from a previous witness about how they do it in other countries. We had evidence about one specific country, actually. We just wondered whether you had any experience of anywhere else that you could direct us to.

Sarah Billington: I personally do not have that experience, although I am aware that papers have been published about other international models of all sorts of different parts of healthcare. I hope Claire has been able to go to international conferences.

Claire Bryce-Smith: I am afraid I have not. I am not aware, but we can ask internally. If we are aware through our policy people—it may well be that our policy people have greater knowledge—we will certainly pass that on to you, if that is helpful.

Q36 **The Chair:** There is still something on my mind. I still have a bit of a problem. I am very grateful for the openness and the way in which you have answered the questions. It has helped us. This is very much a work in progress from our point of view, but I still have a problem, if I think back to our evidence last week. If someone says to me, 'I have had a lousy experience' with anything, I know they could be the only one out of a million, and therefore I do not make a judgment.

That was why, in our evidence session last week, we did not ask three people who had had bad experiences to come and give evidence. We asked very reputable patient groups and a very reputable consultant who works hard to come and talk to us. They described a completely different picture to the one you describe.

What we are trying to do today is understand that. Without asking, I know you will have the utmost respect for the people who gave evidence last week.

Sarah Billington: Yes, absolutely.

The Chair: They must be organisations with whom you work closely. Why did those professionals come to us? They chose to come to London. They did not have to do it. They turned up and gave us that evidence. What are they experiencing that you do not think is right?

Sarah Billington: Those individuals are experiencing poor care.

The Chair: No, they are not.

Sarah Billington: Their patients are.

The Chair: They were representing patient groups. They were not saying, 'Mrs Smith has had a bad time'. We specifically asked them, 'How many of your members has this affected? How long has it been like this?' And it was a lot of people for a very long time. Why have they said that to us when both of you say that everything is quite well? That is what we are struggling with.

Sarah Billington: We are not saying that everything is quite well. The majority of people are experiencing good service. Maybe this is to do with the numbers and volumes involved: 2% of a very large number is a large number.

There will be a significant number of people for whom it has not gone well, for all sorts of reasons. It is great that they have a patient voice to whom they can take their concerns and who can advocate for them. Of course, clinicians are passionate about their patients, and they do hear from their patients, particularly those who perhaps have not had appropriate care or who have had to seek secondary care input because of delays that have caused a deterioration in their condition.

I am speculating as to why they—

The Chair: They are now prescribed in hospital because they know they cannot get the first dose of medicine on the home delivery system within eight weeks. They have to do it in-house. That remains what we are trying to get to the bottom of.

Q37 **Lord Carter:** Can we establish this business about patient satisfaction? The 98.8% is not necessarily an adequate figure. Does the National Health Service run patient satisfaction surveys that capture this? The acute hospitals run it. Do they break it down?

Sarah Billington: They do patient satisfaction surveys. Everybody does. GPs and trusts do those surveys. I do not know whether they would ask that level of detail or give people the opportunity to respond in a freestyle way. We do patient interactions when we are inspecting. We will ask specific questions and hold forums with patient groups.

The Chair: What do you mean by 98.8%? That is those who got their medicines on time, is it not? That is not the same as satisfaction.

Sarah Billington: No, absolutely.

The Chair: Just to be clear, it is not 98.8% satisfaction with the service.

Sarah Billington: Yes, I am sorry. You are right: 98% of patients are receiving their medicines and are not being delayed in their treatment. The experience they had before that happened or during that process is not captured by that statistic.

The Chair: That is what Lord Carter was trying to make clear.

Lord Laming: You can understand that this is very difficult for the Committee. When we have listened to users of services, they have given us a frankly rather dispiriting picture. When we have listened to the providers of services and the regulators, they have given us an entirely different picture, which is that everything is working pretty well or very well.

The Chair: Let me bring in Claire at this point.

Claire Bryce-Smith: I just wanted to say very quickly that I find it a bit perplexing as well. All of our evidence tells us that systemically it is working quite well, but there clearly are some issues. Had we had this conversation in November 2020, when we were experiencing some difficulties with one quite large homecare provider, perhaps our story would have been slightly different.

This is what our evidence tells us. I do find it perplexing that there seems to be a disconnect. I am just wondering whether it is the difference between something that is systemic and something that is more isolated and individual. The numbers might be smaller but very impactful for those individuals. You ask us whether it is systemic. Genuinely, our evidence does not point to it being systemic, but clearly improvements are needed for some. I just wonder about that. I find it quite perplexing.

The Chair: I hate to finish on a perplexing note, but I know the Division Bell is just about to go. You have been saved by the bell. It will stop ringing in a second or two.

If there are any last comments you want to add, could you drop us a note? Otherwise, I will formally close this session. Thank you very much for the time you have given us. It has definitely taken our thinking forward. As we say, we may return, but, if there is anything you want to add to the evidence, please feel free to do so.

Sarah Billington: The only extra thing I would have said is that the system is very fragile and there is not much capacity in it. There is a small number of providers.

The Chair: Thank you very much indeed.