PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Sixth Delegated Legislation Committee

DRAFT MEDICAL DEVICES (CORONAVIRUS TEST DEVICE APPROVALS) (AMENDMENT) REGULATIONS 2021

Wednesday 14 July 2021

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Sunday 18 July 2021

The Committee consisted of the following Members:

Chair: Philip Davies

Andrew, Stuart *(Treasurer of Her Majesty's Household)*
Byrne, Ian *(Liverpool, West Derby)* (Lab)
Caulfield, Maria *(Lewes)* (Con)
Cooper, Rosie *(West Lancashire)* (Lab)
† Dorries, Ms Nadine *(Minister for Patient Safety, Suicide Prevention and Mental Health)*
Double, Steve *(St Austell and Newquay)* (Con)
† Duguid, David *(Banff and Buchan)*
† Furniss, Gill *(Sheffield, Brightside and Hillsborough)* (Lab)
McDonnell, John *(Hayes and Harlington)* (Lab)
† Mak, Alan *(Lord Commissioner of Her Majesty's Treasury)*
Mann, Scott *(Lord Commissioner of Her Majesty's Treasury)*
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
Pursglove, Tom *(Corby)* (Con)
Rees, Christina *(Neath)* (Lab/Co-op)
Rutley, David *(Lord Commissioner of Her Majesty's Treasury)*
Thomson, Richard *(Gordon)* (SNP)
Throup, Maggie *(Lord Commissioner of Her Majesty's Treasury)*

Ben Street, *Committee Clerk*

† attended the Committee

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Wednesday 14 July 2021

[Philip Davies *in the Chair*]

Draft Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

9.25 am

The Chair: I thank Members for observing social distancing, and remind them that Mr Speaker has stated that face coverings should be worn in Committee unless Members are speaking or they are exempt. *Hansard* colleagues will be most grateful if Members could send their speaking notes to hansardnotes@parliament.uk. The eagle-eyed among you will have noticed that, because of the inclement—to a Yorkshireman—hot weather, if people wish to remove their jackets they are welcome to do so.

The Minister for Patient Safety, Suicide Prevention and Mental Health (Ms Nadine Dorries): I beg to move,

That the Committee has considered the draft Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021.

It is a great pleasure to serve under your chairmanship, Mr Davies. Please excuse my opening line—this will be my second pun before 9.30 in the morning—but we live in testing times, literally and metaphorically. The covid-19 pandemic has been a test—for our NHS, for us as a nation, and for everyone. In order to fight the virus, we have had to endure restrictions, but the resolute determination that people have shown during lockdown demonstrates the best of the British character. The amazing performance of our NHS has shown why the UK is stronger united against any storm that may hit these isles. Though many trials have broken upon us, this has not broken us.

As we continue to open up society—spending time with friends and family once again, and enjoying pubs, clubs, football matches and horse-racing—we cannot become complacent about the virus; we must remain vigilant. We are reliant on everyone to protect each other from the virus, and to take responsibility for their health. One in three people with coronavirus show no symptoms and are potentially spreading it without knowing, so testing will remain vital to controlling and containing the spread.

Employers and others are keen to buy their own tests for their staff, to pitch in and do their bit and take pressure off the NHS. I want to empower them to do that, but that requires them to be able to use tests that are at least as good as those in the NHS. However, of 280 tests assessed by the Department of Health and Social Care for public procurement, only 50 were found to reliably detect the virus.

No one wants one bad test kit to reset a year of hard work by giving false negatives that cause people to unknowingly spread the virus once more. That is why we need a strong, independent validation system, with robust enforcement, to enable delivery of reliable, affordable and high-quality tests. First and foremost, any regulations should help protect public health. Strong yet agile regulation for covid-19 tests is essential to that end. As individuals and businesses take on more of a role in our testing effort, it will become a partnership between people, Government and the private sector, with independent validation underpinning trust and confidence in the testing market and remedying the current market failure, to the benefit of both consumers and producers.

It is vital that consumers have clear, comparable information that lets them cut through the confusion and buy with confidence. I want people to know that if they choose to buy tests, the ones available will be as good as those that they would receive on the NHS, so that they can trust the results that they get. That will empower people to take charge and make their own decisions about managing their personal health. This is a chance for producers to show what their tests can do through a fair and equitable system.

Some producers of tests have invested in these technologies in good faith, and feel that they have effective tests that they have successfully trialled with their own processes, but cannot seem to get them validated. Understandably, they question the Porton Down protocols and feel disappointed that they cannot join the procurement frameworks. I hear those concerns and share the frustration, but my message is that our validation processes are the most thorough in the world. Companies often question standards that they cannot meet, but we stand by those standards and will not buy tests that do not meet them. We work with firms to try to get them to the right standard. Patients and taxpayers would not thank us if we bought tests that did not perform to those standards. Self-certification by diagnostic firms is not an approach that has proved reliable during the pandemic.

This statutory instrument, which the Government have laid before Parliament, will establish a clear regulatory regime through which the Government will ensure that all tests on the UK market meet the performance standards set for the NHS. We have experience of validating tests for Government procurement; the regulations build on that expertise to create an agile regime that will validate all polymerase chain reaction and lateral flow tests that meet those standards. We are confident that this will enable the ongoing supply of high-quality tests to the UK market.

The regulations set clear performance thresholds, which provide rigorous yet fair criteria that industry will have to meet by undergoing an expert review. Manufacturers should see that as an opportunity to have their products tested, and to get feedback. It is an opportunity to have high-quality scientific advisers assess the product, and then to allow businesses to make it a race to the bottom, minimising costs while they take advantage of the pandemic to maximise their profits. We will publish a register of tests that pass validation, along with other information that is clear and comparable. Empowered by that information, consumers and companies can make informed and prudent choices when buying kits for themselves, their families or their workforce.

We intend the regime to recover its costs primarily from manufacturers, rather than being supported by taxpayers. However, I am conscious of the concerns raised during the consultation that fees set too high

could be a barrier to small and medium-sized manufacturers entering the market. We firmly recognise the important, innovative contribution our small and medium-sized enterprises make. We have implemented a discount for such businesses, so that their dynamism, creativity and nimbleness continue to bring new tests to market to meet the changing needs of people and businesses.

Industry will require time to adapt to our new regulatory requirements. We have balanced the need to give industry reasonable time against the need to remedy the market failure. To strike this balance, I have instituted phased grace periods for those manufacturers who work with us. This will mean any tests already on the market will be able to remain there if the manufacturers do what is required of them. I have clearly set out that they have until 1 September 2021 to register their tests for the validation process.

They will then have until 31 October to complete and pass the process.

The diagnostic device manufacturers in the UK include a few big players, but 90% are small and medium-sized enterprises. We have implemented a discounted fee for them, so that they continue to bring new tests to market, and meet the changing needs of people and businesses. I am confident that any well-run company with a quality product can meet the lower fee of £6,400.

No one wants a regulatory wasteland, full of failed businesses, where we are entangled by distrust, disreputable weeds grow, and consumers have to beware with every step. Good regulation helps to ensure a well maintained garden where businesses thrive and blossom into success, where there is trust between buyers and sellers, and where consumers are safe to explore.

I do not see passing these regulations as the end; it is merely the beginning. I will add to the regulations later this year with a further laboratory stage, underpinned by a second statutory instrument. That will also provide an opportunity to consider emerging issues. Beyond that, my officials will continually engage with stakeholders to ensure that the process is as smooth as possible, and will conduct a review next year, which I will lay before the House. The review will provide recommendations on how to refine the regulations, and on what lessons we can learn to help bolster the diagnostic legacy of this pandemic.

The BMJ highlighted the importance of early diagnostics, and set out why we need a sea change to our approach to disease management once the pandemic passes:

"Poor diagnostic preparedness has contributed to significant delays in the identification of recent outbreaks for multiple pathogens, including Ebola, Lassa fever, yellow fever and Zika, primarily due to poor local diagnostic capacity. In the case of the 2013–2016 Ebola epidemic in West Africa…postoutbreak analyses suggest that diagnosing 60% of patients within 1 day instead of 5 days could have reduced the attack rate from 80% to nearly 0%. In the end, it was diagnostics information coupled with appropriate interventions that led to eventual containment of the outbreak, but the delays resulted in the loss of thousands of lives and billions of dollars in the cost of response."

It is clear that long-term benefits come from a thorough testing culture, and the challenge going forward is to deliver the latest innovations at affordable prices. I want our regulations to help manufacturers rise to this challenge, and to leave a diagnostic legacy that does not just improve our everyday health but makes us more resilient in dealing with winter flu and challenges in the decades ahead.

9.35 am

Alex Norris (Nottingham North) (Lab/Co-op): It is a pleasure to serve under your chairship, Mr Davies, and to be part of the proceedings that make first use of a new power under the Medicines and Medical Devices Act 2021; it feels like a long time since we were sitting in a similar Committee Room debating that Act. I am grateful to the Government for the briefing session for Members of both Houses last week, in which we were able to ask a number of important questions.

High-quality testing is a crucial part of fighting coronavirus. Knowing who has it and who they have been in contact with, and supporting them and their contacts as they isolate themselves, is a core way of preventing transmission. Even as we start to reopen significant aspects of British life, that basic principle will remain with us for some time, so it is right that testing be put on a high-quality, properly regulated footing. While members of the public are not at direct risk from bad tests, the knock-on impact of a false positive or negative is serious, so we need to set up a regime that reduces the risk of that as much as possible. Of the 280 tests available, only 50 would pass the relevant standards. That is sobering, and good reason for us in this place to act. We therefore do not intend to divide the Committee, but I would like details from the Minister.

The explanatory memorandum describes the regulations as "urgent" action. We are some 16 months into this crisis, and the powers have been available under the 2021 Act for some months; is this the fastest the response could have been? When the regulations were considered in the other place earlier this week, there was a suggestion that the reason for the new-found urgency was that the Government wish to transition to a charging model of testing, rather than the current public health model in which tests are made widely available for free. Lord Bethell said that was not the case; I am hoping that the Minister will give the same commitment, and will say that free testing will be available after the regulations are approved next Monday, and while we deal with the current peak of infections.

The Minister talked about a partnership going forward. I understand that the Government cannot be expected to carry the entire burden indefinitely, certainly not for private entities, but what will that partnership look like for the rest of this year? Assuming that we do not lose free tests in the short or medium term, there is an expectation that we will start to see an increase in testing through the private route. I did not hear, in the Minister's opening speech, assurances on how those tests will be linked to NHS Test and Trace. There is value in testing in and of itself—it lets individuals know whether they need to self-isolate—but the point of having a central system is that we can have surveillance around the virus, and critically we can seek contacts and get them to isolate, too. Will the obligation still be on the individual, and will there still be support from the state?

I asked this at the briefing but did not get a particularly detailed answer, so I will try again. On the fees regime, we support, of course, the discount for small and medium-sized enterprises, which make up the bulk of the market, as the Minister said. In general, though, that £14,000 figure seemed quite high, not to mention suspiciously rounded, for a full cost recovery model. Will she share the breakdown

[Alex Norris]

of the costs? If she does not have that information with her, perhaps she might put it in the Library, because there is interest in it.

The instrument allows the Secretary of State to exempt tests on a case-by-case basis to avoid supply issues for the NHS. However, tests procured by the Department of Health and Social Care or the NHS are exempt already, so why is that necessary? The main weakness of the 2021 Act was that it allowed too much regulation to be implemented or set aside at the stroke of a pen by a Minister acting as a Caesar, rather than as someone who is accountable to Parliament. There does not seem a lot of point in doing what we do, either downstairs or up here, if a Minister can later decide that they are not interested in a certain provision of a regulation or Act. That should be avoided as much as possible, and I cannot see its value in this case. I may be missing the point, but I hope the Minister will address that, or at least say what safeguards will be put in place, and what reporting there will be of the provision's use.

In a growing market such as this, there will still be some who choose to break the rules, thinking it a route to quick profit. Presumably the enforcement will be for the Medicines and Healthcare products Regulatory Agency. Is it suitably resourced to tackle this in the short term, as it beds in? Will it have a specific team on it? Similarly, what will the fines regime look like, and will it compound for repeat offenders?

To finish where the Minister finished, the shadow Health Secretary, my right hon. Friend the Member for Leicester South (Jonathan Ashworth), is fond—I wish he was not so fond—of saying that we are in an era of pandemics. I am not attracted to that characterisation, but as the Minister put it, disease management is something that, globally, we clearly have to get much better at. This may not be the last time that we deal with something like this. The points that she made on the management of the Ebola virus were very interesting. On future-proofing, how portable is this model for testing in future pandemics? Or will it hold merely for covid-19? Rather than waiting 16 months, we would be able to implement it much more quickly.

As I said, I do not intend to divide the Committee. I know that I have fired off a number of questions. I hope that, if the Minister does not have all the information today, she might be able to follow up in writing.

9.42 am

Ms Dorries: I was furiously trying to write down all the questions, because there were a lot in rapid succession. I am afraid I did not get them all down—the hon. Member was too fast.

Why now? I think I have said before to the hon. Member in Committee that we started at zero. We started with nothing—with no tests—when the global pandemic landed on our shores. It does not take a great deal of imagination to understand that we have been running to catch up, including by developing tests, Test and Trace, vaccines, isolation techniques and local management outbreak plans. The whole management of covid has been a mammoth effort.

The market is dominated by free tests from NHS Test and Trace, with the exception of tests for international travel. Obviously, there are exceptions. I am glad that the hon. Member noted what I thought was the most important part of my speech. There are other pandemic outbreaks that we can learn from, such as Zika, Ebola and yellow fever. The post-pandemic analysis shows us that if, in those examples, there had been more diagnostic post-pandemic testing, deaths could have been down to almost 0%. That is obviously where we need to move to. As we come out of the pandemic, we need to learn from the examples of pandemics of the past, and need testing that meets our high standards to be available to anyone or any organisation that needs or wants it. As I said, our standards are the highest in the world, and we will continue to maintain them.

Now is the time, coming out of the pandemic, when we need to put this in place, so that anyone or any organisation that wants to be additionally vigilant as we open up can be. The hon. Member asked me to confirm what Lord Bethell mentioned in a debate—I do not know when that was. Access to the NHS is part of the overall offer for individuals who want to access testing. However, businesses and private venues that want to put in place their own measures for the protection of their staff, for international travel and for opening up will also have access to tests.

I think the hon. Gentleman then asked another question; officials will have taken a note, and we will respond to him. On how we will ensure that test results are reported, it is a legal requirement that where a test is conducted by a testing provider, the result, whatever the outcome, be reported to Public Health England—or the UK health security agency, as it will be. This must be done within 24 hours, because covid is a notifiable disease; under the framework of that legislation, PHE has to be notified of any test result. We will know the results of those tests.

I am confident that the regulations are a proportionate and appropriate measure to ensure that all PCR and lateral flow tests available across the UK will, as I mentioned in relation to Porton Down, meet the same world-leading standard—a standard of which we should be proud. Being free to set our own regulations allows the UK to innovate, and to create agile yet strong regulations that can set new standards. Other countries will be watching how we do it. We have done it with vaccination; they will be watching how we manage post-pandemic, and how we manage testing. That new approach to regulation gives businesses seeking to enter the UK market the certainty they need, while providing strong safeguards for consumers.

British manufacturers and pharmaceutical research and engineering firms have led the way in the global effort to combat the virus, keeping the NHS supplied with kits, tests and medicines over the past year. The UK should be proud of how it has risen to the challenge of the pandemic. We have grown our diagnostics capability dramatically: we now have a total laboratory capacity of 6 million PCR tests. The Government have to date administered 214 million tests in total, delivering well over a million tests daily. The UK now has one of the largest diagnostics capabilities in the world.

We have also supported the growth of the private market through the accreditation of testing service providers. There are now more than 1,200 private providers of general testing, with the United Kingdom Accreditation Service administering the accreditation process. Regulating services is only half of the market; we must also regulate

the goods side. We estimate that around 97 million CE-marked lateral flow device test kits reach the UK domestic market per week, and that capacity is growing. Because of that growth, it is important to get this regulatory regime in place now. We need to make sure the regulation is there to provide standards and to support growing markets, particularly in the arts and culture, and the workplace generally.

As we look forward to a future in which we can once again spend time with friends and family, enjoy the arts and sport, and work and shop as we once did, we must remain vigilant against the virus. It will still be there. We all have a part to play in keeping each other safe, and we have a duty towards our families, friends and colleagues. Testing is vital to that new paradigm. No one wants false negatives, which cause people unknowingly to allow the virus to spread. A mandatory validation scheme will not limit the supply of high-quality tests. Rather, the policy will ensure that poorly performing test kits that would not have helped our collective effort to combat covid-19 can be identified and removed from the market. They simply will not pass the test.

I regret that we are considering the regulations without an accompanying impact assessment and opinion. The timescales have meant that we have not yet been able to produce an IA with which the Regulatory Policy Committee is content. We continue to work with the RPC to ensure that we have a robust assessment of the impact for inclusion in the business impact target, although we accept that that assessment will come too late to have been of use in this debate. I am grateful to the RPC for the effort it has put into accommodating our timescales. We are working so thoroughly on the evidence and analysis for the IA, as the Government are clear that we want to be a world leader in agile regulation. This will likely encourage businesses to locate more research and/or manufacturing in the UK. It is clear that the regulatory regime that we are debating will provide only benefits for the safeguarding of public health, and certainty for businesses.

To some, this may seem a radical intervention in the market, but I am reminded of John Snow, the father of epidemiology. When the evidence is clear and change is needed quickly, radical action is no vice; it is a virtue. That change could be as simple as removing a pump handle, as Dr Snow did to prove that the source of cholera was in London's water supply, or acting to ensure consistent standards that bring the best of business creativity to bear for the public good. This is the benefit of agile regulation. It does not force businesses on to particular paths of innovation, constraining them with costly rules that deter risk-taking. Instead, it adapts to keep consumers safe.

Having been on various Statutory Instrument Committees over the 17 months of the pandemic, I can say that this is one of the more positive SIs that I have had the pleasure to present, knowing as I do that it will bring about collective good and assist us with our post-pandemic preparedness.

Question put and agreed to.

9.51 am

Committee rose.