PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Ninth Delegated Legislation Committee

DRAFT MEDICAL DEVICES (NORTHERN IRELAND PROTOCOL) REGULATIONS 2021

Thursday 15 July 2021

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The Committee consisted of the following Members:

Chair: Dr Rupa Huq

† Argar, Edward *(Minister for Health)*
† Caulfield, Maria *(Lewes)* (Con)
Crosbie, Virginia *(Ynys Môn)* (Con)
Cryer, John *(Leyton and Wanstead)* (Lab)
† Furniss, Gill *(Sheffield, Brightside and Hillsborough)* (Lab)
Harman, Ms Harriet *(Camberwell and Peckham)* (Lab)
Harris, Rebecca *(Lord Commissioner of Her Majesty's Treasury)*
Jones, Mr Marcus *(Vice-Chamberlain of Her Majesty's Household)*
Mak, Alan *(Lord Commissioner of Her Majesty's Treasury)*
Mann, Scott *(Lord Commissioner of Her Majesty's Treasury)*
Mishra, Navendu *(Stockport)* (Lab)
† Morris, James *(Lord Commissioner of Her Majesty's Treasury)*
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
Pursglove, Tom *(Corby)* (Con)
Rutley, David *(Lord Commissioner of Her Majesty's Treasury)*
Thomson, Richard *(Gordon)* (SNP)
Trickett, Jon *(Hemsworth)* (Lab)

Joanna Dodd, Bethan Harding, *Committee Clerks*

† attended the Committee

Ninth Delegated Legislation Committee

Thursday 15 July 2021

[Dr Rupa Huq *in the Chair*]

Draft Medical Devices (Northern Ireland Protocol) Regulations 2021

11.30 am

The Chair: Before we begin, I remind hon. Members to observe social distancing and sit only in places that are clearly marked—I think this is the last time we are saying this; it will not apply from Monday. I also remind Members that Mr Speaker has stated that masks should be worn in Committee. That does not apply to me because I might have to say something at any second. Our colleagues in *Hansard* would be most appreciative if you emailed your speeches to hansardnotes@parliament.uk. I call the Minister to move the motion.

The Minister for Health (Edward Argar): I beg to move,

That the Committee has considered the draft Medical Devices (Northern Ireland Protocol) Regulations 2021.

It is a pleasure to serve under your chairmanship, Dr Huq.

Today we are debating an instrument that is necessary to maintain the regulatory landscape for medical devices in Northern Ireland following a change in European Union law. It reflects the recent application of Regulation (EU) 2017/745 on medical devices in Northern Ireland, which applies to all general medical devices, but not to in vitro diagnostic medical devices. For simplicity, I will hereafter refer to the EU medical devices regulation. I draw the Committee's attention to the fact that this instrument does not itself cause the EU medical devices regulation to apply within Northern Ireland. That legislation took automatic effect in Northern Ireland on 26 May this year under the terms of the Northern Ireland protocol.

Through this instrument, the Government deliver their commitment to the pragmatic implementation of the protocol by introducing provisions that minimise the impact of the EU medical devices regulation on economic operators and the public in Northern Ireland. The EU medical devices regulation contains some areas where states have the discretion to make their own policy choices. This instrument therefore legislates in those policy areas, and where possible seeks to align the position in Northern Ireland with that in Great Britain. The Medical Devices Regulations 2002—hereafter referred to as the 2002 regulations—will continue to be the relevant regulations for in vitro diagnostics devices in Northern Ireland. They will operate alongside the EU medical devices regulation itself and this instrument on the regulation of general medical devices.

The instrument achieves the Government's commitment to align Northern Ireland with Great Britain where permitted in four areas. First, it implements national adjustments for Northern Ireland in areas where the EU medical devices regulation grants member states the ability to make national policy decisions. This has been done in a way that will align with policies in place in Great Britain. Secondly, it sets out the fee structures that keep fees charged by the Government aligned with those applied in Great Britain. Thirdly, the instrument sets out the enforcement regime for activity and violations under the EU medical devices regulation in Northern Ireland. Finally, it makes an amendment to existing regulations so that they take account of the application of the EU medical devices regulation in Northern Ireland.

Several aspects of this instrument are, as will become apparent, technical. I therefore might not be able to address all the elements in detail in the time that we have available. I will, however, provide the Committee with details on the most important provisions. I will first set out the provisions that the instrument makes to change default positions under the EU medical devices regulation where permitted.

Re-manufacturing single-use devices, which the EU refers to as reprocessing, is currently permitted in the UK as long as the re-manufacturer adheres to strict requirements. The EU medical devices regulation does not permit re-manufacturing, but grants member states the ability to make national allowances, which this instrument also does for Northern Ireland. That means that the re-manufacturing of single-use devices can continue to take place in Northern Ireland as it does in Great Britain as long as all requirements of the EU medical devices regulation are adhered to.

The instrument also introduces provisions so that the Medicines and Healthcare Products Regulatory Agency can continue to require the registration of custom-made devices. That means that a range of devices such as, for example, dental appliances or orthopaedic moulds must be registered before being placed on the Northern Ireland market, as is currently the case in Great Britain.

The instrument also ensures continued alignment between Great Britain and Northern Ireland so that the safety of participants continues to be protected in clinical investigations. It does so by maintaining the MHRA's ability to authorise clinical investigations for all risk classes of medical devices before they can commence. It also upholds the requirement for custom-made-device clinical investigations to be subject to MHRA assessment.

As well as these provisions, which amend the default positions of the EU medical device regulation where permitted, this instrument also sets out the fees that the MHRA may charge for activity under the EU medical device regulation in Northern Ireland to continue covering the costs associated with certain aspects of the regulation of medical devices. All fees outlined in this instrument are identical to those charged for similar services in Great Britain under the 2002 regulations, thereby maintaining alignment.

The Government are maintaining identical fees as part of our commitment to ensure that, where possible, there are no disadvantages to economic operators in Northern Ireland as a result of the protocol. To that end, no new fees are introduced in this instrument for any new requirements under the EU medical device regulation.

The enforcement provisions introduced in this instrument provide the Secretary of State with enforcement powers to ensure that patient safety is prioritised and high standards are maintained for the people of Northern Ireland. It does so by creating a specific offence that relates to breaches of certain provisions of this instrument

and of the EU medical devices regulation; by amending the Medicines and Medical Devices Act 2021 and the Consumer Rights Act 2015; and by granting the MHRA and district councils in Northern Ireland inspection powers and powers to serve enforcement notices for breaches of the EU medical device regulation within Northern Ireland. These powers allow the MHRA to respond to concerns and to constantly deliver improvements to patient safety.

Finally, the instrument includes technical amendments to other legislation, including the 2002 regulations, to reflect the application of the EU medical device regulation within Northern Ireland. In doing so, it ensures that the regulatory landscape operates effectively in Northern Ireland.

I should put on the record that I am grateful for the continued collaborative approach of officials in the Northern Ireland Executive, who have been kept informed of and engaged with the progress of this instrument. I also inform the House that, due to the very technical nature of this instrument, it has not met the threshold for an impact assessment and therefore one is not provided.

By introducing this instrument we are upholding the Government's commitment to minimise the impact of the Northern Ireland protocol on the activities of the public and economic operators in Northern Ireland. The pandemic has shown that public health considerations are more important than ever, and by introducing this instrument we are taking steps to ensure that the UK's exceptional standards of safety continue to be maintained within Northern Ireland.

I commend the instrument to the Committee.

11.37 am

Alex Norris (Nottingham North) (Lab/Co-op): It is a pleasure to serve under your chairship, Dr Huq.

The Minister and I have had a touring show in Committee, implementing various parts of the Northern Ireland protocol, and this instrument is very much in the same vein. However, unlike the Minister himself, the Northern Ireland protocol is not ageing well. *[Laughter.]*

Lord Frost said last week that it is wrong to view the Northern Ireland protocol as a "definitive" text. I would say that when we consider instruments of this nature—I have done an awful lot of them now—the things that we are doing feel rather "definitive", and it is an extraordinary failure of statecraft to characterise an agreement that the UK entered into willingly in this fashion. I recommend that hon. Members read the transcript of the consideration of this instrument in the other place. It is quite something to read the level of criticism of the status of Northern Ireland now with regard to instruments such as this one, with much of it coming from some of those who were the most enthusiastic about our embarking on this course in the first place.

So why are we here today? As the explanatory memorandum says, it is not to implement the EU medical devices regulation, which came into effect from 26 May; Northern Ireland has taken those rules in a way that the Government said it would not have to. Within that regulation, there is latitude for individual countries to diverge from the MDR where national law differs and in the areas that the Minister talked about: on single-use devices and custom-made devices, we differ. This instrument is therefore necessary to ensure that we can do that across the whole of the United Kingdom. Of course, we support that idea, so I will not seek to divide the Committee today. However, I will briefly pick up a few points with the Minister regarding alignment, enforcement, and the conformité Européenne or CE mark more broadly.

First, the instrument addresses the fact that, although the EU MDR is fully applied, our MHRA remains the regulator. Therefore, we need to give it—again, this is why we support the SI in front of us—provisions for enforcement of fees and so forth where national divergences exist, so that we can have alignment. However, I wonder what this will mean in practice for the people of Northern Ireland. What impact will there be if the European Medicines Agency and the MHRA depart markedly from each other's regulatory regimes, and what would that mean for businesses and their products? What conversations has the Minister had with colleagues in the Northern Ireland Executive?

While the Northern Ireland protocol is in effect, and very definitively so, a CE mark is required to go to market. That is potentially advantageous for patients in Northern Ireland versus those in Great Britain, as the vast majority of products—for example, 600,000 medical devices—that have been approved in the EU are already CE-marked across the whole of the UK. That would continue to be the case under the protocol, but the situation could change in Great Britain after 2023. Indeed, I believe that the plan is to introduce the new UK(NI) mark. At the moment, we have access to 600,000 devices with the CE mark, but we do not know what the plan will mean in years to come.

Will the Minister give some detail about parliamentary opportunities to scrutinise and improve plans for the relationship between the CE mark and the UK(NI) mark? That will become a fundamental question of patient safety across the UK in years to come, and we really ought to have a very strong plan for it, all lightness aside, even if there are elements of the Northern Ireland protocol that the Government think will be dropped at some point. This element definitely will not be, because it is a core part of our medical devices regime going forward. We would benefit from having more opportunity to discuss that point.

On enforcement, the SI will give the MHRA powers to serve notices for breaches of the EU MDR, so manufacturers will need to take a number of steps to ensure that their goods can still be sold after the deadline, as noble lords mentioned in great detail when they considered the SI. What discussion and consultation have the Government had with the sector? I agree wholly with the judgment that the SI does not pass the threshold for an impact assessment, but ongoing consequences may do so in the future, so I am keen to know what sorts of questions the Government have received.

My final point is on an issue that I raise every time we have a matter relating to the MHRA, but I am never quite sure that we get a strong answer. There was a similar issue in Committee yesterday. What enforcement capacity does the MHRA really have for the range of duties that it has acquired through our exit from the European Union, through the Medicines and Medical Devices Act 2021, through the SI on coronavirus tests that we discussed yesterday, and through the responsibilities picked up in the SI we are debating? Are there more people doing enforcement than there were three years

[Alex Norris]

ago, when none of those responsibilities existed? Is the funding for that on a sustainable footing? Is it something that can be built around? Can people be trained and developed and become real experts on this issue? We will need that to have a secure regime, because we will lose all our protections from working in a flock with our colleagues on the continent. The Minister mentioned that the SI does not apply to in vitro devices and that we still rely on the 2002 regulations. Are there plans to update that in due course?

This is the tip of a bit of a whopper of a mess. Approving the SI is the right thing to do today to ensure that, to the best of our ability, Northern Ireland can be part of our medical devices regime. In the conversations that we are having outside this place on issues relating to this matter, the central question should always be patient safety, but the central question is now about borders and bureaucracy, which is what we were told it would not be about. I hope the Minister can address my questions.

11.44 am

Edward Argar: As ever, I am grateful to the shadow Minister—not only for adopting a typically sensible and pragmatic approach to these issues, but for his kind, if perhaps slightly inaccurate words, about my greying hair and my ageing.

The regulations are particularly about allowing the Government to meet their commitment to implement the Northern Ireland protocol, and doing so in a pragmatic way to minimise the impact on the activities of the public and, indeed, operators in Northern Ireland. We believe they do this while—quite rightly, as the hon. Gentleman said—maintaining the highest standards of patient safety for the people of Northern Ireland, as we would expect right across the United Kingdom.

One of the shadow Minister's key themes was regulatory divergence and differences. As a Government, we are committed to adopting a pragmatic approach to regulatory divergence, seeking to minimise impacts wherever possible. He will have seen, from what I said just now, that the changes contained in this instrument are essential to delivering on that by providing, where possible, consistency and continuity between regulations in Northern Ireland and Great Britain, where of course we are not constrained by the EU medical devices regulation.

The shadow Minister raised a specific point about the scrutiny of CE and UK(NI) marks. As an experienced Member of Parliament, he will know that there will be many opportunities for the Opposition to table debates on these issues, either in the main Chamber or in Westminster Hall. If they wished to do so, Ministers—probably me—would be delighted to continue our touring double act on issues relating to the implementation of the trade and co-operation agreement and the Northern Ireland protocol.

The shadow Minister also talked about conversations and engagement with the Northern Ireland Executive, industry and others. That engagement continues on a wide range of topics relating to the Northern Ireland protocol and, more broadly, the implementation of the TCA, including continuity of supply and how industry is finding the implementation of the protocol. Not only have fora been hosted within the Department across the broad range of industry suppliers and the bodies representing them, at which we discuss these issues and seek out their views, but in the case of Northern Ireland and the Northern Ireland Executive, as I mentioned, we are very grateful for the collaborative working at an official level on these regulations and on other aspects of the implementation of the protocol. I have regular—at the moment, almost monthly—virtual meetings with my opposite number, Robin Swann, the Minister of Health in Northern Ireland. We discuss a range of topics, and as one would expect, the implementation of the protocol and measures such as these are among them so that we ensure as smooth an implementation and a result for the people of Northern Ireland as possible.

The shadow Minister mentioned the Northern Ireland protocol more broadly, and his views on the Government's approach to it. It has always been the case throughout history that once international treaties and agreements are reached, tweaks are made to ensure they can be practically implemented on the ground. That is nothing new. It is true of treaties throughout history, and that is what we continue to work with our colleagues in Northern Ireland and the Commission to address.

Turning briefly to possible areas of regulatory divergence—I know this area has interested the shadow Minister in other debates on regulations—as I said, the instrument generally retains all the requirements of the directives it repealed, and indeed adds some additional ones to ensure consistency with GB. Those include additional rules for the designation of notified bodies, additional control and monitoring requirements for competent authorities, and additional clarifications of the roles of different economic operators. The EU medical devices regulation reclassifies some devices and has a wider scope than the directives. That includes devices for sterilising other medical devices and certain devices with no evident intended medical purpose, which is annex XVI of that regulation. A new unique device identification system is also introduced to enhance traceability and post-market activities related to safety. Additional requirements are also introduced for the publication of information on devices and clinical and performance studies relating to their conformity, and the new European database for medical devices and in vitro diagnostic medical devices—which I think the shadow Minister mentioned, and which I will come on to in a second. EUDAMED is also introduced to make data available in increased quantity and quality.

The UK will shortly consult on the future of the Great Britain medical devices regulations, which will benefit patient safety and access. That work on the future GB regulatory regime will explore any risks around regulatory divergence between GB and NI in that context. I hope that addresses the shadow Minister's concerns, but I can reassure him that there will be opportunities for this issue to be debated and discussed—more broadly in the House, but probably in Committees such as this—when we get to that point.

I hope I have dealt with at least the majority of the shadow Minister's points, but if there are any others he wishes to raise, he knows that he is always welcome to write to me. With that, I commend the regulations to the Committee.

Question put and agreed to.

11.50 am

Committee rose.