PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Ninth Delegated Legislation Committee

DRAFT HUMAN MEDICINES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

DRAFT MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

Thursday 26 November 2020

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not later than

Monday 30 November 2020

The Committee consisted of the following Members:

Chair: Andrew Rosindell

† Argar, Edward *(Minister for Health)*
Beckett, Margaret *(Derby South)* (Lab)
Betts, Mr Clive *(Sheffield South East)* (Lab)
Brennan, Kevin *(Cardiff West)* (Lab)
Bryant, Chris *(Rhondda)* (Lab)
Butler, Rob *(Aylesbury)* (Con)
† Caulfield, Maria *(Lewes)* (Con)
† Charalambous, Bambos *(Enfield, Southgate)* (Lab)
† Daly, James *(Bury North)* (Con)
Double, Steve *(St Austell and Newquay)* (Con)
† Eastwood, Mark *(Dewsbury)* (Con)
† Fletcher, Mark *(Bolsover)* (Con)
Grady, Patrick *(Glasgow North)* (SNP)
† Henry, Darren *(Broxtowe)* (Con)
Holden, Mr Richard *(North West Durham)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Richards, Nicola *(West Bromwich East)* (Con)

Seb Newman, *Committee Clerk*

† attended the Committee

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Thursday 26 November 2020

[Andrew Rosindell *in the Chair*]

Draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2020

11.30 am

The Chair: Good morning. Before we begin, I remind Members to observe social distancing and only sit in places that are clearly marked. *Hansard* colleagues would be most grateful if all Members sent their speaking notes to hansardnotes@parliament.uk after the sitting.

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

That the Committee has considered the draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2020.

The Chair: With this it will be convenient to consider the draft Medical Devices (Amendment etc.) (EU Exit) Regulations 2020.

Edward Argar: It is always a pleasure to serve under your chairmanship, Mr Rosindell.

The statutory instruments concern the regulations for human medicines and medical devices. They form part of a legislative programme to ensure there is a functioning statute book at the end of the transition period to provide certainty for businesses and the public. Most of the changes they make are technical in nature.

It is a pleasure, as ever, to serve in Committee opposite the shadow Minister, the hon. Member for Nottingham North. We have become something of a double act in these Delegated Legislation Committees covering the legislation for the end of the transition period.

I believe that everyone in this Committee Room shares the Government's intention to protect patient safety and preserve patients' access to innovative new treatments. That could not be more important than in the context of the covid-19 response. The statutory instruments have been developed to maintain our world-leading standards in the regulation of medicines and medical devices now that we have left the European Union and as the transition period comes to an end.

The statutory instruments broadly achieve three things: they make minor amendments to existing regulations to take account of the implementation period agreed under the withdrawal agreement; they implement our obligations under the Northern Ireland protocol; and they implement specific policy changes to the regulatory regime in Great Britain to ensure that the regulatory framework is up-to-date and functioning correctly at the end of the transition period. The regulations do not prevent the need for future changes, but preserve the solid foundations of the UK regulatory environment to ensure patient safety—something I suspect the shadow Minister will speak about—and to ensure that the UK remains one of the best places in the world for science and innovation.

I will mention briefly the most notable policy changes that the instruments set out in law, for the benefit of Members. The instruments are long and technical, so I am unable to address all elements of them in the time available, but I will endeavour to cover the main points.

The medical devices instrument will allow us to maintain the current standards of regulation. We will ensure that patient safety and health outcomes are not adversely impacted, and we will continue to recognise the CE marking on medical devices and in vitro diagnostic devices, which have demonstrated their conformity with EU regulatory requirements, for a further two and a half years. That approach is both sensible and pragmatic. It provides time for industry to adapt to future regulations and eliminates any delay in access to devices for UK patients, while maintaining continuity.

A policy change that I note for the Committee is the adoption of the new conformity assessment marking for medical devices. The Government have created their own product safety marking, which will be used across goods regulation. The UK conformity assessment—UKCA—mark will be available for industry to use for devices placed on the market in Great Britain from the end of the transition period.

The medical devices instrument, as it applies to Great Britain, removes certain provisions from the previous EU exit instrument, which would have inserted regulations similar to the EU's medical devices regulation, or MDR, and in vitro diagnostic regulation, or IVDR. That is because the full application of the two EU regulations will now fall outside the transition period.

The independent medicines and medical devices safety review, which delivered its report in July, highlighted the importance of strengthened regulations that do more to protect patients. The regulations, as amended by the medical devices instrument, will be built on using the powers of the Medicines and Medical Devices Bill, which is currently continuing its passage in the other place.

The Bill will provide the opportunity to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety and innovation. Our plans are in development, and will take into consideration both international standards and global harmonisation in the establishment of our future system. We will of course consult closely with stakeholders within the life sciences and healthcare sectors on that future regime.

I now turn to the human medicines instrument to note a few further changes that will help the UK to maintain its excellent regulatory system for medicines and clinical trials. From 1 January 2021, marketing authorisations granted by the EU will continue to apply in Northern Ireland; however, all medicines to be placed on the market in Great Britain must be authorised through the UK national route.

The human medicines instrument allows the Medicines and Healthcare products Regulatory Agency to have regard to decisions taken by EU member states on products approved via decentralised and mutual recognition procedures when considering whether to authorise those products in Great Britain. That policy is to ensure that the UK can continue to take effective regulatory and safety action on those products.

The instrument will also ensure that novel and innovative medicines continue to come to the UK market after the end of the transition period. That will be achieved by

allowing recognition of decisions by the European Medicines Agency to grant UK marketing authorisations for centrally authorised products.

Both the human medicines and the medical devices instruments uphold the Prime Minister's commitment to unfettered access for Northern Ireland's businesses to the whole of the UK market. In doing so, they provide for transparency requirements for medicines and medical devices moving from Northern Ireland to Great Britain, which will allow the MHRA to maintain oversight of products on the GB market and thus protect patient safety.

For medicines, the MHRA will still retain regulatory powers, such as carrying out a targeted assessment of a medicinal product where it is deemed necessary for safety reasons. For medical devices, non-UK manufacturers placing devices on the UK market will be required to appoint a UK responsible person. The UK responsible person will be required to register devices with the MHRA in accordance with a transitional timetable set out in the regulations.

To fulfil the requirements of the Northern Ireland protocol, both instruments make relevant changes to ensure that the relevant EU laws will continue to apply in Northern Ireland after the end of the transition period and, additionally, the instruments grant the MHRA powers to continue to regulate medicines and devices in Northern Ireland in order to ensure that there is clear continuity for patients and businesses.

Members will be aware that the MHRA charges fees to cover the costs associated with the regulation of medicines. To reflect the regulatory changes that will take effect after the transition period ends, the instrument reduces some of the fees to ensure that they will still be commensurate with the cost of the work performed by the MHRA.

The devolved Administrations have been kept informed of the drafting of the instrument, and I put on record my gratitude for their continued collaborative approach. In particular, I thank the Minister of Health in Northern Ireland, Robin Swann, who agreed, despite policy for human medicines being a devolved matter, that the human medicines instrument should be signed solely by the Secretary of State for the Department of Health and Social Care.

We have also been working closely with industry through the development of the statutory instruments. In September and since then, we have published a number of guidance documents that go into further detail on those changes on gov.uk. We have held an accompanying series of webinars to engage directly with more than 11,500 industry representatives, providing them with an opportunity for their questions to be asked and answered. My officials continue to meet regularly with the major industry suppliers and key trade associations, including the Association of the British Pharmaceutical Industry, the BioIndustry Association and the Association of British HealthTech Industries.

It is also important to note that the instruments amend pre-existing EU exit legislation made in 2019, taken through on behalf of the Opposition, I think, by the hon. Member for Ellesmere Port and Neston (Justin Madders)—the other half of the Opposition double act on these instruments. A full consultation process was conducted for the pre-existing legislation and, moreover, full impact assessments were conducted for the underlying legislation.

As the nature of the changes in the instruments that we are discussing today are in many instances technical, the impact of the instruments, above and beyond the existing legislation, is not assessed to meet the threshold for further impact assessments; hence they have not been provided for. I commend the draft regulations to the Committee.

11.39 pm

Alex Norris (Nottingham North) (Lab/Co-op): It is a pleasure to discuss these instruments under your chairship, Mr Rosindell. As the Minister says, we have had a rolling tour of them in recent weeks, but happily we seem to have a rotating supporting cast, other than the Whips, so I can just about get away with repeating some of the same arguments.

I will start, as always, by saying that we are getting very close to the final opportunity for the deal with the EU that the Government promised to finalise. I know that business desperately wants no deal to be taken off the table, and will be looking at the proceedings with interest. Perhaps the Minister will update us on the progress. I suspect that he will say it is "ongoing", as he generally does.

As has been set out, the draft regulations amend the post-Brexit regulatory framework for medicines and medical devices respectively to implement the Northern Ireland protocol and ensure that the UK meets its related obligations under that agreement. That is, of course, a necessary step towards maintaining the UK's obligations—necessary, critically, to ensure that people are kept safe when using medicines and medical devices.

We will not divide the Committee, but I have a few areas where I would like greater clarity. At the heart of this is patient safety, which is important to all of us; however, I think we have detected a waning in the Government's commitment in this area in recent months. It has now been four months since Baroness Cumberlege published the independent medicines and medical devices safety review. Campaigners for that review were ignored and derided, some for many decades, but with the publication of that report they were vindicated.

We are four months on. Frankly, the Government have sat on it. Campaigners got an apology on the first day, but have been unable to get a word out of the Government since. We cannot get anything by the written question route either. It is exceptionally disappointing. I know that the Government have a lot on, but the failure even to pick up the phone to talk to those who suffered and give them an update adds insult to injury. I speak to people affected each week, and they are heartbroken by the Government's response.

Will the Minister make a commitment that he will prod and urge his relevant colleague to consult campaigners as a matter of urgency? I honestly would not let the day finish without doing that. The hurt is really significant. Will he also commit the Government to using the remaining stages of the Medicines and Medical Devices Bill to implement the relevant recommendations? It is a perfect vehicle for us to act quickly, and we really ought to do so.

[Alex Norris]

The first set of draft regulations, regarding human medicines, amend the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, as the Minister said, as well as the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019. The 2019 regulations themselves amended the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Medicines (Products for Human Use) (Fees) Regulations 2016. They set out what the basis for the regulation of medicines and clinical trials will be in Great Britain from 1 January, and the draft regulations ensure that the 2019 regulations will remain effective at the end of the implementation period, which is, as I say, very important.

As well as making some technical amendments, the instruments will reverse some of the changes made by the 2019 regulations to limit them to Great Britain, while EU law will remain in effect in Northern Ireland, and implement policy changes to Great Britain's regulatory regime only. As we would expect, EU marketing authorisations will now authorise sale or supply in Northern Ireland only, and UK marketing authorisations will no longer automatically apply for the whole of the UK. That often gets lost, but it is a very significant change.

I understand that the MHRA will have provision to pay regard to decisions taken by EU member states when making licensing decisions, but could the Minister explain what impact he thinks it will have on the MHRA in terms of the burden of its work when authorising products entering Great Britain? Will there be extra checks? Will there be extra pre-assessments?

Similarly I understand that, due to industry feedback, products used in clinical trials, investigational medicinal products, will no longer need to be certified by a qualified person—a QP—at both ends, which presumably would have increased the administrative burden twofold. Instead, the whole of the relevant UK manufacturer's authorisation for import licence will simply have to ensure that any IMP has been QP certified by someone based in an approved country. There is a year before that comes into place, but could the Minister guarantee that it will not have a significant impact on the safety of the investigational products and of those using them in the trials? If so, how does he know that, and on what basis has he formed that decision?

Changes are made to a number of areas, but time is limited and I need to move on to the other draft regulations. I will conclude on this element with a slightly more general question. For absolute on-the-record clarity, can the Minister say that he is confident that the changes will not make users of medicines less safe, or leave UK businesses in a situation where they cannot compete? Those are the two points very much in play. I do not think that anybody, either in this room or in the country more generally, thinks that either of those possibilities would be a good thing, so clarity on the record about the judgment that he has made on that would be very helpful.

The draft medical devices regulations also amend the 2019 regulations to ensure that the regulatory landscape is fit for purpose at the end of the implementation period and, importantly, to keep us safe. Schedule 1 amends the principal regulations to ensure that devices placed on the Northern Ireland market meet EU legislation under the protocol. It also makes provision for persons placing devices on the market in Northern Ireland to register devices and for manufacturers of devices to appoint a UK responsible person where there is no other presence.

We talked much about the UK responsible person when considering the Medicines and Medical Devices Bill, because we know that there have been sharp practices previously. I am keen for the Minister to provide clarity and to commit to ensuring that people are not using responsible persons in name only. We know of examples of a single person, who seems to have very little connection to the businesses, being the responsible person for all manner of products, when their employment is in no way related to them. I am keen to hear any reflections on that.

The Minister discussed the UK conformity assessed marking. This is, of course, a significant moment. The assessments will be carried out by UK approved bodies, which will be converted from UK notified bodies by this instrument. What impact will that change have on the bodies and their capacity to make conformity assessments?

We support the continuation of the CE marking. That was a wise decision by the Government. I am interested to hear how the period of two and a half years was arrived at. I would like to hear an on-the-record commitment from the Government that there will be no risk to the supply of medical devices as a result of the conformity assessment.

Finally, the explanatory memorandum states:

"The MHRA will seek to minimise the legislation's impact by providing guidance".

Will the Minister say when that will happen and what other steps are being taken to support the MHRA in this process? The MHRA, which has always been important, is now a crucial body.

When it comes to the safety of medicines and medical devices, we are now on a high tightrope. We used to have the common eyes of the notified bodies of our EU partners looking at our products; now we will look at them alone. That is the decision that has been taken, but it means that if there is one mistake, there is no backstop. It would therefore be much appreciated if the Minister gave a sense of the capacity of the MHRA and its readiness to take on what is an absolutely crucial function.

11.47 am

Edward Argar: I am grateful to the shadow Minister for his typically reasonable and measured comments. He repeated a number of questions that are familiar to me, but he did not repeat his jokes from previous Committees, which is a relief for hon. Members. I will deal with his points in order.

In respect of a deal or a future relationship agreement, the hon. Gentleman knows me very well and can predict my response. I will, of course, say to him that the negotiations continue, and it would be wrong to prejudge them. However, I know that Her Majesty's Government continue to negotiate actively and positively with the European Union.

The hon. Gentleman is right in his key point about the importance of patient safety. I reassure him that the Minister for Patient Safety, Mental Health and Suicide

Prevention is, as he will know, a passionate advocate for patient safety. She takes it incredibly seriously both in her role as a Minister and given her background in medicine and nursing—it is deeply important to her. As I speak, I suspect she is on the Front Bench with my right hon. Friend the Secretary of State. I will certainly pass on the hon. Gentleman's request and comments in respect of the Cumberlege review when I see her after the statement.

The hon. Gentleman reflected on a number of other factors. He often asks me in these Committees, quite reasonably, whether we are going to deliver our obligations under the Northern Ireland protocol. I reassure him that this is the penultimate Delegated Legislation Committee—we have one more to go—in fulfilling this Department's obligations under the protocol by putting through the necessary regulations.

The hon. Gentleman asked for reassurances. I reassure him that I am confident that these statutory instruments and the regime that follows the end of the transition period will not make patients less safe and will not have a negative impact on our life sciences sector and businesses. The whole approach we are adopting in this country is to strengthen patient safety and put it at the heart of what we do, while also supporting our fantastic life sciences sector and its competitiveness and innovation. I reassure him of my confidence that we will continue to deliver on those objectives.

On responsible persons, the hon. Gentleman rightly said it is important that that process and that individual do the job they are there to do, and do it properly. He mentioned the period of two and a half years on top of the transition period. That was reached in discussion with industry about what it needs and with the regulators about how to make the transition to a new regime effective.

Finally, the hon. Gentleman talked at length about the MHRA and asked several questions, so I will spend a few minutes responding to them. He will be aware that the UK has substantial capacity and expertise to regulate and evaluate the quality, safety and efficacy of medicines and medical devices. The MHRA is expert in many areas, including the licensing of medicines, pharmacovigilance and clinical trials regulation. That already provides benefits to patients. The MHRA is the lead regulator on more than 3,500 medicines currently on the EU market.

The hon. Gentleman asked about the impact on the MHRA and its workload. I reassure him that it will receive additional funding of just under £13 million by the end of March next year to help it prepare for the end of the transition period and meet its obligations under the regulations. Among other activities, that is being used to fund investments in new and improved IT systems to enable better regulation of medicines and medical devices in Northern Ireland under the protocol. It has also contributed to additional staffing requirements to manage all aspects of the new regime to which he alluded.

The MHRA is taking robust steps to ensure that it is ready to continue to perform, as it always has done, at the highest level, putting patient safety first, and we have given it the resources to do that.

Question put and agreed to.

DRAFT MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

Resolved,

That the committee has considered the draft Medical Devices (Amendment etc.) (EU Exit) Regulations 2020.—*(Edward Argar.)*

11.52 am

Committee rose.