PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Sixteenth Delegated Legislation Committee

DRAFT HUMAN MEDICINES AND MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

Monday 7 October 2019

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not later than

Friday 11 October 2019

The Committee consisted of the following Members:

Chair: Mr Peter Bone

† Bottomley, Sir Peter *(Worthing West)* (Con)
† Campbell, Sir Alan *(Tynemouth)* (Lab)
† Cooper, Julie *(Burnley)* (Lab)
† Dorries, Ms Nadine *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Double, Steve *(St Austell and Newquay)* (Con)
Forbes, Lisa *(Peterborough)* (Lab)
† Hair, Kirstene *(Angus)* (Con)
Huq, Dr Rupa *(Ealing Central and Acton)* (Lab)
Johnson, Diana *(Kingston upon Hull North)* (Lab)
† Jones, Andrew *(Harrogate and Knaresborough)* (Con)
† Maclean, Rachel *(Redditch)* (Con)
Mahmood, Shabana *(Birmingham, Ladywood)* (Lab)
Spellar, John *(Warley)* (Lab)
† Sturdy, Julian *(York Outer)* (Con)
† Throup, Maggie *(Lord Commissioner of Her Majesty's Treasury)*
† Tomlinson, Michael *(Mid Dorset and North Poole)* (Con)
Whitford, Dr Philippa *(Central Ayrshire)* (SNP)

Jo Dodd, *Committee Clerk*

† attended the Committee

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[Mr Peter Bone *in the Chair*]

Draft Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

6.15 pm

The Parliamentary Under-Secretary of State for Health and Social Care (Ms Nadine Dorries): I beg to move,

That the Committee has considered the draft Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

It is a pleasure to serve under your chairmanship, Mr Bone. Hon. Members will be aware that in March this year the House considered and approved the statutory instruments that aim to ensure that our national regulatory system for medicines and medical devices continues to function appropriately in the event that the UK leaves the EU without a deal. Before us today is a draft statutory instrument that makes additional changes to that legislation in areas that my Department has identified would benefit from further clarification. This is being done in response to comments from stakeholders, including the industry and the life sciences sector, and from internal review.

I reiterate that the Government's position remains that the UK would prefer to leave with a deal, and we continue to work towards that. However, the Government are also committed to preparing for an outcome in which a deal is not reached and we have to leave the EU without a deal.

I reassure all hon. Members that, as the former Minister said in March, the Government are fully committed to a system of medicines and medical devices regulation that intelligently balances patient access to new, innovative and world-leading products with protecting UK patients from harm. The Medicines and Healthcare Products Regulatory Agency, as part of these measures, will have in place a suite of licensing routes for medicines and vigilance systems for medicines and devices. The UK Government also place enormous value on the contribution to public health of research charities, the industry and the life sciences sector as a whole. The MHRA will therefore continue to support innovation in the life sciences through its innovation office and scientific advice. We are committed to offering a competitive regulatory environment to ensure that the UK has access to the safest and most effective medicines and medical devices.

The fundamentals of how medicines and devices are regulated will remain the same, in terms of the UK's regulatory system. Where possible, we have sought to maintain existing arrangements rather than to create any new ones. However, there are a few areas where it has been necessary to add a new requirement, and we have consulted the industry and other stakeholders on our proposals in those areas. These regulations will ensure continuity in the area of medicines and medical devices in a no-deal EU exit. This legislation does not prevent future changes that we may wish to make to ensure that the UK maintains an appropriate regulatory environment and remains one of the best places in the world for science and innovation.

The Department's priorities have been to ensure that timely availability of safe and effective medicines and medical devices continues, while minimising disruption to patients and businesses, and ensuring that the UK regulator is able to continue to protect public health. That continues to be the case with this SI.

I will now give hon. Members some more detail about the arrangements set out in these regulations. I must emphasise that the proposed changes are technical in nature and do not represent any change to underlying policy. The instrument corrects minor drafting errors and seeks only to ensure that the original policy intention is delivered. Specifically, for medicines it includes the following. First, it clarifies that the requirements for a responsible person for import and wholesaler's licences apply to hospitals importing human medicines for their own use directly from a country on an approved list.

Secondly, it clarifies that UK generic applications can rely on data supplied in relation to medicinal products whose EU marketing authorisations were cancelled pre-exit on grounds other than safety, quality and efficacy.

Thirdly, it introduces additional detail in relation to the process by which companies may make representations to the Commission on Human Medicines about decisions on rare disease medicines and paediatric matters.

Fourthly, it includes the provision of a temporary exemption, subject to specific conditions, from the obligation to maintain a UK pharmacovigilance system master file for companies whose UK authorisations are included in an EU file. That also includes the condition that information required by the licensing authority is provided by the marketing authorisation holders on request.

Fifthly, it includes the clarification that the temporary exemption as to the geographical location of an appropriately qualified person for pharmacovigilance applies to all the marketing authorisations and herbal registrations a company holds, whether granted before, on or after exit day. That is provided that they are covered by a single pharmacovigilance system in respect of which there is the same qualified person.

Finally, it includes the addition of the Republic of Korea to the approved list of countries with equivalent regulatory standards for the manufacturing of active substances on exit day, which reflects updates to the EU list since the no-deal SI was made.

For medical devices, some changes result from the amendments made by the EU to the underlying EU medical devices regulations via the recently published corrigendum since the no-deal SI was made. The changes are minor or technical corrections. Two further changes are inserted to ensure that products used mainly for cosmetic purposes are required to comply with common specifications and to require the information registered with the MHRA about medical devices to be updated by the manufacturer.

In conclusion, in the event of a no-deal exit, the regulations will minimise any impact on patients and business to ensure the timely availability of safe and effective medicines in the UK market by putting in

place changes that will ensure that the UK's legislation in these areas continues to function effectively from day one.

6.21 pm

Julie Cooper (Burnley) (Lab): It is a pleasure to serve under your chairmanship, Mr Bone. I thank the Minister for outlining the detailed changes in the new regulations and for underlining their importance.

The regulations certainly are important, given that we are only 24 days away from a potential no-deal Brexit. A parliamentary majority has three times voted to oppose the UK crashing out of the EU with no deal. Hon. Members, including me and others on the Opposition side of the House, did not do so on a whim or as part of some political game, but because all the evidence, including the Government's impact assessment, makes it clear that leaving the European Union without a deal would be catastrophic for the UK in general.

Indeed, no area gives greater concern than the provision of medicines and medical devices. There can surely be no issue more important than ensuring that patients have timely access to the safest and most effective medicines and medical devices. Some 60% of prescription and over-the-counter medicines supplied in the UK come from or via the EU. It is vital for patients that that access is uninterrupted, so it is exceptionally worrying that the Government's Yellowhammer papers warn that medical supplies could be delayed for up to six months.

The British Medical Association is worried about the provision of medicines and medical devices in the event of a no-deal Brexit. It has urged the Government to consider that:

> "Many medicines, including life-saving agents for cancer diagnosis and therapy, cannot be stockpiled and for those that can, stockpiles could run out";

that such delays can lead to fatalities; and that

> "No responsible government should take that risk."

Can the Minister respond to that point and outline some of the specific contingency plans that the Government have put in place for medical supplies that cannot be stockpiled, such as radioisotopes used in the treatment of cancer patients? What guarantees can she give that radioisotopes will continue to be imported into the UK without delay in the event of no deal? What further contingency steps has the NHS taken to ensure that radioisotopes will be supplied uninterrupted to hospitals across the UK?

Given the importance of the legislation, one has to wonder why it is not in place at this late hour. I have a sense of déjà vu because, as the Minister said, it was only in March that the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 were debated. At that time, my hon. Friend the Member for Ellesmere Port and Neston (Justin Madders) put on the record our grave concerns about the widespread and totally inappropriate use of secondary legislation for such important and potentially controversial matters. Secondary legislation is not fit for this purpose, not least because it does not provide the opportunity for detailed scrutiny.

Back in March, my hon. Friend the former shadow Minister warned that the process was not robust and that rushing through the legislation with inadequate scrutiny would lead to mistakes and omissions. Here we are today, required, according to the Government's accompanying explanatory notes,

> "to correct drafting defects and omissions in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791)."

My hon. Friend was absolutely right. The situation is extremely worrying. It begs the question of how many more omissions and defects in this regulation are yet to be revealed.

I know everyone on both sides of the House is keen to ensure that all aspects of retained EU law in relation to human medicines and medical devices operate effectively and are not deficient after exit day as a result of the UK's withdrawal from the EU. The stakes are high, and this legislation will have far-reaching effects on the multi-billion-pound pharmaceutical industry, medical device companies, wholesalers and all those in the supply chain. If we do not retain a close working relationship with the countries of the EU that closely emulates the one that we have enjoyed for many years through the European Medicines Agency, opportunities for research, innovation and access will be restricted. Most importantly, this could have a devastating effect on our NHS, potentially affecting the lives of millions of patients.

We support the Government's desire to give the UK protection in all these areas, so we will not oppose this SI, but we want to put on the record our grave concerns about the way they have gone about this. We are appalled by the Government's late attention to this most serious of matters. The Government have known since 2016 that there were risks, and for much of the past three years they have taken no action. We are horrified by the shambolic process that has led us at this late stage to be addressing omissions.

These regulations go beyond technical corrections and the correction of key acronyms; they clearly make substantive amendments and raise more questions than they answer. Let us look at some of the specific corrections. I hope that the Minister can clarify some important points.

There is provision here for a mechanism for companies affected by proposed decisions of the licensing authority in relation to orphan medicines to have those decisions reviewed by the Commission on Human Medicines. The question is how long that process will take. Where the criteria are satisfied, how long will it take for supplies to be sanctioned? How will timely supplies be guaranteed? What protections will be in place to protect patients in the UK from fake medicines?

In relation to the treatment of rare diseases, can the Minister clarify what provision she has made to support UK patients who rely on the European Research Network for the diagnosis and treatment of their rare diseases, if a no-deal Brexit leads to our expulsion from the network? What will the Government do to ensure that the UK can continue to participate in EU-wide clinical trials in the event of a no-deal Brexit?

The changes to the regulations allow for the introduction of a transitional period relating to the system for pharmacovigilance. Effective pharmacovigilance must be at the heart of the new arrangements, ensuring the health and safety of patients and, crucially, increasing the benefits of medicines. I understand that businesses

[Julie Cooper]

will need time to comply with the new regulations, but what protections will be in place for patient safety during this interim period?

What estimate has the Minister made of the cost to the industry of establishing the presence of a qualified person responsible for pharmacovigilance for those companies that do not already have a UK presence? That will inevitably involve costs for establishing premises, familiarisation and administration to ensure compliance with the new legal requirements. Does she intend to ensure that the Government meet those costs? While answering that point, perhaps she could also take this opportunity to advise on the planned provision for extra resources that will be needed by the Medicines and Healthcare Products Regulatory Agency to enable it to carry out its extensive new responsibilities.

The new regulations deal with the very important matter of medicines for children. These are not mere technical changes. The regulations introduce paediatric investigation plans. Can the Minister explain exactly what these will entail and how long the process will take? Will it lead to delays in supplying medicines and medical devices? Will additional training for staff be required? What extra resources will the process require and where are those resources coming from? Will it mean any delay in the development or availability of medicines?

The Chair: Order. I am sorry to interrupt the hon. Lady. I know that this room is not ideal for a Committee, but officials are not supposed to pass notes directly to a Minister.

Julie Cooper: These points all prompt a question: why are these changes not accompanied by a new impact assessment? Our constituents will be listening to this debate and fearing that these changes will lead to poor or delayed supplies. They will be worried, and they are right to be. For some people this will be a matter of life or death. This is not "Project Fear"; this is a genuine fear that patients will be put at risk. The BMA has said:

> "Disruption resulting from the UK crashing out of the EU without a deal on 1 November will cause 'irreparable harm' to the NHS and catastrophically exacerbate the challenges posed by a winter pressures crisis."

It went on to say:

> "We are not 'the doubters, the doomsters or the gloomsters' the Prime Minister described on the steps of Downing Street. Nor is this 'Project Fear'. We are doctors who day in and day out provide care for patients in the face of challenges that will only be made worse by a 'no deal' Brexit in the critical winter months following 31st October. We have a duty to speak out about matters that can harm patient care and we will continue to highlight the dangers Brexit presents in the weeks and months ahead."

We will not oppose these regulations today, but we will record our grave concerns and seek answers to the specific questions that have been put. I agree with the medical professionals, and for the sake of the health and wellbeing of the citizens of the UK I urge the Minister to join me in heeding their warning, and I urge the Prime Minister to avoid a no-deal Brexit and instead work on constructive transitional arrangements in the context of an organised exit.

6.32 pm

Ms Dorries: I will not comment on the hon. Lady's opening comments about a no-deal exit, because obviously we are where we are, we all stood on a manifesto to honour the result of the referendum, and it is not my position to comment on a no-deal exit.

I will answer the hon. Lady's more specific points. It is important to make the point that at any one time in the UK there is a shortage of over a hundred medicines, and that has absolutely nothing to do with Brexit, as I am sure she knows. It can be to do with fires in factories, or a downturn in supply from abroad. At any one time there are shortages, and any shortages today have nothing to do with Brexit.

Julie Cooper: I absolutely agree with what the Minister has just said. I have personal experience of pharmaceutical provision in the UK and I know that what she has just said is true. However, does she not agree that exiting the EU with no deal will exacerbate existing problems?

Ms Dorries: The hon. Lady will not be surprised to know that I do not agree, because I believe—I cannot guarantee, but I believe—that all efforts are being made and all arrangements are in place to ensure a supply of drugs into the UK. Under just-in-time arrangements, drug companies would have a stockpile of a week's supply, but now all drug companies have stockpiled six weeks' worth of medications to be used in the UK, and I do not envisage a shortage of any drug that is required.[1] Obviously, I cannot guarantee that—that cannot be done—but every effort has been made by every Department and every official and in every negotiation with drug suppliers and pharmaceutical companies to ensure that they have a six-week supply ready for a no-deal Brexit. We do not see any problem with that.

The hon. Lady referred to drugs with short shelf lives, which cannot be stockpiled. In that instance, arrangements have been made for those drugs to be air freighted into the UK. She mentioned isotopes in particular. They cannot be stockpiled, but they will be airlifted into the UK, so we will see absolutely no shortage of isotopes either. I am sure that we can provide further information on that, but I hope that, now that hon. Members are aware that drugs that have no shelf life will be airlifted, we will not hear those stories. What worries me, and what worries many people, is the public perception when they hear stories that there will be no isotopes because they cannot be stockpiled. We must take our responsibilities very seriously here.

Julie Cooper: I can assure the Minister that I take my responsibilities in this very seriously. I know that many hon. Members here do too—including her, I am sure. But this is not just a case of political to-ing and fro-ing, trying to create a sense of panic in the community about this. When the medical professions are leading the voices of concern, surely the Government should be listening to their worries.

Ms Dorries: I assure the hon. Lady that we do, and I hope that they will see today's debate and be reassured that there will be no shortage of drugs with short shelf lives, because they can be airlifted in.

1. *[Official Report, 14 October 2019, Vol. 666, c. 1MC.]*

The hon. Lady also asked how we can be confident that there are no more mistakes. I think she is referring to the grammatical errors and various technical errors that occurred in the previous SI, which was 700 pages long and very technical in its content. Those issues were not identified at the time by any party or any individual, but they have now been identified. The amendments that this new SI makes to the previous SI are minimal and include updates to the underlying EU regulations that have been brought forward since the original SI was finalised.

This particular SI has also undergone legal checking and been scrutinised by the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee, and we are confident that it will ensure that these regulations operate effectively after exit day. If the hon. Lady does not feel that she has had enough detail, we will provide anything in writing as a back-up.

The hon. Lady asked what paediatric investigation plans mean. This SI does not introduce paediatric investigation plans; they are already required by EU legislation. The previous no-deal SI simply transferred functions relating to those plans from the EU to the MHRA. She also asked why there was no impact assessment. There are no new policies in this SI, so there is no need for a further impact assessment. The MHRA ran a four-week public consultation and published an impact assessment on the previous SI. This SI ensures that the policies implemented are in line with the consultation and the responses to it.

On the protection of patients, the hon. Lady asked about an interim period relating to a transitional period for a pharmacovigilance system. The new proposed transitional period is for the pharmacovigilance system master file, which will be held in the UK. Companies will be required to operate a pharmacovigilance system from exit day. The master file is in the description of the pharmacovigilance system and the amending SI, which includes statutory contributions associated with a temporary exemption, to ensure supervisory capability of the companies, the QPPV and the MHRA.[1] I think that she also mentioned the safety aspects. Each pharmaceutical company will be required to have safety staff in the UK in line with this.

The hon. Lady asked whether new and innovative medicines would be delayed in the UK under a no-deal scenario. The MHRA intends to provide free scientific advice for UK-based small and medium-sized enterprises and has introduced a new targeted assessment procedure to authorise medicines as soon as possible following an EMA-positive opinion. In addition, it will often accelerate an assessment route to enable licensing more quickly than in the EU. The MHRA would monitor application volumes in a no-deal scenario.

I thank the hon. Lady for her valuable contribution to the debate. As promised, we will get back to her with further information in writing if she requires it. I am confident, as was the case in March, that we have a shared intention to protect and improve the safety of patients using medicines and medical devices, while enabling their access to the most innovative treatments.

Our regulator, the Medicines and Healthcare Products Regulatory Agency, has more than 30 years' experience as a leading regulator in the EU. That expertise and experience is globally recognised and respected, and we want to ensure that continues, to the benefit of all UK patients. It is with that at the forefront of our minds that the UK's plans for the regulation of medicines and medical devices in a no-deal scenario have been developed.

Question put and agreed to.

6.40 pm

Committee rose.

1.*[Official Report, 14 October 2019, Vol. 666, c. 1MC.]*