PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Third Delegated Legislation Committee

DRAFT HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) (EU EXIT) REGULATIONS 2019

DRAFT QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2019

DRAFT HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019

Wednesday 19 December 2018

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not later than

Sunday 23 December 2018

The Committee consisted of the following Members:

Chair: Graham Stringer

† Charalambous, Bambos *(Enfield, Southgate)* (Lab)
† Coaker, Vernon *(Gedling)* (Lab)
† Day, Martyn *(Linlithgow and East Falkirk)* (SNP)
† Doyle-Price, Jackie *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Eagle, Maria *(Garston and Halewood)* (Lab)
† Flint, Caroline *(Don Valley)* (Lab)
† Foster, Kevin *(Torbay)* (Con)
† Heaton-Jones, Peter *(North Devon)* (Con)
† Hodgson, Mrs Sharon *(Washington and Sunderland West)* (Lab)
† Huddleston, Nigel *(Mid Worcestershire)* (Con)
† McKinnell, Catherine *(Newcastle upon Tyne North)* (Lab)
† Mak, Alan *(Havant)* (Con)
† Morris, David *(Morecambe and Lunesdale)* (Con)
† Morton, Wendy *(Aldridge-Brownhills)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Philp, Chris *(Croydon South)* (Con)
† Throup, Maggie *(Erewash)* (Con)

Dominic Stockbridge, *Committee Clerk*

† attended the Committee

Third Delegated Legislation Committee

Wednesday 19 December 2018

[Graham Stringer *in the Chair*]

Draft Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

8.55 am

The Parliamentary Under-Secretary of State for Health and Social Care (Jackie Doyle-Price): I beg to move,

That the Committee has considered the draft Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019.

The Chair: With this it will be convenient to consider the draft Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 and the draft Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019.

Jackie Doyle-Price: It is a pleasure to serve under your chairmanship this morning, Mr Stringer—even though it is a bit early for some of us.

We are debating three sets of regulations that will be critical to maintaining patient safety in respect of organs, tissues and cells used to treat patients as we leave the European Union. They are no-deal statutory instruments: they have been developed as part of contingency planning and will be needed in the event that we leave the EU with no agreement in place. If the UK reaches a deal with the EU, the Department will revoke or amend the instruments to reflect the deal. The instruments will ensure that UK law on organs, tissues and cells functions effectively after exit day and maintains the same high standards of safety and quality. The instruments are being made under the European Union (Withdrawal) Act 2018. They make appropriate amendments and revocations to correct deficiencies in UK law and retained EU law.

I will go through the amendments in detail. First, in the event of no deal, the UK and the EU will consider each other to be third countries; the regulations redefine the term "third country" to include EU countries and Gibraltar. As a result, licensed establishments will need to make administrative changes to continue to import organs, tissues and cells from EU countries and Gibraltar.

A small number of organs are shared with EU and non-EU countries, with fewer than 30 organs on average being imported or exported each year. Despite the small numbers, we need to ensure that an appropriate legal regime is in place. Tissues and cells are imported from and exported to EU countries less often than they are imported from and exported to countries outside the EU. There are about 5,000 imports of tissues and cells from the EU in a typical year. That includes about 600 imports of stem cells and 3,000 imports of bone products. The UK imports donated sperm primarily from commercial sperm banks in the USA and Denmark.

Secondly, the regulations amend a number of references in current UK legislation that will no longer be appropriate once the UK withdraws from the EU. That includes references to obligations with which the UK must comply as an EU member state and some references to the EU, the European economic area, the European Commission and EU law. The regulations also modify how some of the requirements in the directives, which are referred to in domestic legislation, are to be read post exit.

Thirdly, these instruments propose a conferral of powers from the Commission to the Secretary of State and the devolved Administrations, where that is within devolved competence, permitting the Government to respond to emerging threats, changing safety and quality standards and technological advances. Legislative competence for the donation, processing and use in treatment of human reproductive cells—sperm, eggs and embryos—is reserved to Westminster. Competence in respect of all other human tissues, cells and organs is devolved; the relevant instruments are being made on a UK-wide basis, with the agreement of the devolved Administrations. The proposed amendments have been fully discussed with the Scottish, Welsh and Northern Irish devolved Administrations, and they have given formal consent to the draft statutory instruments.

The instruments are intended to maintain the current regulatory framework, so that UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics will continue to work to the same standards that they worked to prior to our leaving the EU. The impact of the instruments on businesses and public bodies will be low. Only establishments that import from or export to EU countries will be affected.

There is no impact for organ transplant centres. NHS Blood and Transplant and the Human Tissue Authority are working together to ensure that the new arrangements are put in place properly. Licensed establishments that import tissues and cells will need to put in place new agreements, so that they can continue to import tissues and cells from EU countries. The draft regulations give a six-month transition period so that they can do so. UK regulators will continue to advise and support all tissue establishments in preparing for exit day.

The draft regulations will allow us to continue with business as usual while leaving the European Union. I commend the draft regulations to the Committee.

9 am

Mrs Sharon Hodgson (Washington and Sunderland West) (Lab): It is a pleasure to serve under your chairmanship, Mr Stringer, and to be in this room to discuss these draft regulations.

It concerns me that we have to have contingency plans in place in the event of a no-deal Brexit. I certainly hope that all of us in this room would prefer us to leave with a deal, so that we can have an element of certainty. However, in lieu of any certainty, I understand and acknowledge that the draft regulations are very much needed and are the next option. I am sure that the public will also be concerned. What assurances can the Minister give patients, who will inevitably be concerned about these contingency plans? Will she give assurances that the draft regulations will retain—and in some cases even improve—patient safety?

I understand that the draft regulations will come into effect on 30 March 2019 in the event of a no-deal Brexit. However, these changes must be effectively communicated to the affected agencies in a timely manner. Do the Government have a deadline for doing that? The draft Human Tissue (Quality and Safety for Human Application) regulations include a six-month transition period, with provisions to ensure that imports may continue while licences and agreements are put in place. Can the Minister please elaborate on what those provisions will consist of?

The draft regulations must not affect the safety, quality or supply of organs, tissue or cells. We know how the healthcare system depends on there being a constant supply of those, so it is crucial that there is no interruption in that. Hopefully, the draft regulations will not be needed—but if they are, I hope that all these issues will have been considered by the Government.

9.2 am

Martyn Day (Linlithgow and East Falkirk) (SNP): It is a pleasure to serve under your chairmanship, Mr Stringer. I appreciate that these are emergency draft regulations, and I will not oppose them, but I think it is madness that we have been brought to the point of having to rush through hundreds of these regulations because of the Brexit process. All this could have been avoided if we had stayed in the single market and customs union or—better still—if we were not leaving the EU at all.

However, I have one question. We do not know what the exact process will be for licensed establishments to apply for a new import-export relationship. The Government need to make that process clear as soon as possible, so that those establishments can prepare if they need to. Will the Minister elaborate on that?

9.3 am

Maria Eagle (Garston and Halewood) (Lab): May I say what a pleasure it is to be here this morning serving under your chairmanship, Mr Stringer? I concur with the questions and remarks of my hon. Friend the Member for Washington and Sunderland West, and with the question from the hon. Member for Linlithgow and East Falkirk.

I have one or two questions for the Minister about some of what I have seen in the draft regulations and the explanatory memorandum. She rightly says that only a small number of organs are shared between EU and non-EU countries, with fewer than 30 organs imported or exported on average. However, the draft regulations will come into force in a no-deal scenario, in which there will be no transition period and all the borders will go up. Only a small number of organs might come and go, but they are vital; many are a matter of life and death for the individual who will receive them. What arrangements has her Department made to make sure that those organs can get through?

The Government's own preparedness documents suggest that there are going to be queues at borders. It is very easy to see how this kind of time-critical matter could get caught up in bureaucracy at borders. I know that the regulations are just about making arrangements, but I did not find anything in the Minister's remarks or the explanatory memorandum to say what contingency arrangements the Government were making to ensure that the organs get through. That time-critical matter is often one of life and death. I would be grateful if the Minister said something about that.

There is no impact assessment because the Government have taken the view that the financial impact is lower than the £5 million threshold for which such documents are prepared. It would be helpful to have some idea of the extra cost that the arrangements provided for by these instruments would impose on the authorities that take on the job currently done by the Commission. Do the Government intend to reimburse them the extra money that that will cost? A six-month period is provided in the instruments for the new administrative arrangements, if necessary, to be made, but there is no reference—and the Minister did not make one—to whether the Government intend to reimburse those authorities for the extra work.

A small number of organisations import and export human tissue and organs, but I do not know how many there are. Can the Minister tell us and have the Government been talking in detail with them about precisely what they will need to do? There is the six-month period, but what precisely will those organisations have to do? I would be grateful for a little more detail from the Minister before we take a view on these instruments.

9.7 am

Vernon Coaker (Gedling) (Lab): It is a pleasure to serve under your chairmanship, Mr Stringer. I agree with the comments made by everyone. We are all disappointed that we are where we are and that we have to come forward with these measures, although it is only right, given where we are, that we make contingency plans. In line with my hon. Friend the Member for Garston and Halewood, I believe it would be helpful for the Committee to have a bit more detail.

As the Minister said, only a small number of organisations are involved, but if someone needs an organ, cornea or cell, that is a critical matter. Without the support of masses of civil servants, it is difficult to understand the situation. Will the Minister confirm that there is no change in anything here—it is just a simple transposition of law? Will she also confirm that the Secretary of State has gained no additional powers? A huge number of regulatory powers are given to the Secretary of State.

There is sensitivity around these issues and the Acts referred to; we know about the debates on embryology, reproduction and research. Has anything changed in that area? References to a subsection of a subsection of a subsection sometimes mean that there is a change somewhere. The Minister's confirmation would be helpful. My hon. Friend mentioned the transition arrangements of six months. What happens at the end of that if nothing has changed?

I had to look for the technical note. That was not referred to, yet it includes important information that relates to the SI. For example, it says:

> "Further information on the agreement process will be published in November."

I cannot find that further information. Has it been published? What are the written agreements? Who is supposed to be making them? Again, I am not opposed to what the Minister is saying, but if it says on her own website that further information will be published, where is it? My hon. Friend has obviously been looking for it, too.

[Vernon Coaker]

The website also says:

"We'll be publishing more information and instructions on putting written agreements in place in November 2018."

Presumably, individual companies are supposed to be producing these written agreements, not the Government. So what has happened with those companies? Do they know? What discussions have taken place with them?

I have been reading in the media today that business is expressing a lot of concern—whatever the rights and wrongs of where we are—about what they are, or are not, supposed to be doing. Given the importance of this matter, who is producing these written agreements?

The website goes on to say:

"The aim is to give organisations, businesses and individuals as much certainty as possible, as soon as possible, and to ensure that any new requirements are not unduly burdensome."

To be honest, Minister, the Committee could have done with seeing what the information is—given that it was supposed to have been published last month, and given its importance. Some clarity on that would be really helpful.

The technical note also says that

"This notice is meant for guidance only",

but then goes on to say:

"You should consider whether you need separate professional advice before making specific preparations."

I do not know what that means. Why would anyone need separate professional advice if everything was carrying on exactly the same as before? The situation has just moved on and people should just carry on. I would be grateful if the Minister clarified what the separate professional advice is. As my hon. Friend has just asked, who is paying for that?

I come to my last point. Yesterday, the Department published a note on funding for different health organisations, entitled:

"EU Third Health Programme funding if there's no Brexit deal".

Are all the organisations affected by this SI going to receive funding under that health programme funding arrangement, so that they can address some of the issues that will arise if there is no deal, which we all hope will not be the case?

Clearly, this is an important SI. As my hon. Friend has said, these SIs are all hugely important, because down the road we will suddenly find that something has changed or that there should have been a written agreement—even though it is on the website, nobody has asked what those written agreements actually are or what they are supposed to contain. Again, I would be grateful if the Minister clarified some of that.

9.13 am

Caroline Flint (Don Valley) (Lab): It is a pleasure to serve under your chairmanship, Mr Stringer. My hon. Friends have made very pertinent points about the draft regulations, and I absolutely agree with the contribution from the Front Bench by my hon. Friend the Member for Washington and Sunderland West.

I used to be Public Health Minister, and this is one of the policy areas I used to cover. Does the Minister agree that one of the aspects of this subject is the contribution the UK has made to wider EU policy in this area? Some of the standards we have set have been very positive in promoting wider understanding among the 27 countries, plus us, in the European Union about the necessity for safety and precaution in this area.

Unfortunately, we have heard terrible stories about how lax systems can lead to all sorts of consequences for individuals and for health policy generally. The UK and some other EU members have played a positive part in addressing that. Does the Minister agree that, in many respects, although we are transposing this policy into UK law, it is actually a law that we were at the forefront of pushing in the first place?

It is absolutely right that the Government should take a precautionary approach to ensure that, in the event of no deal, we have adequate provisions on the statute books to continue to provide services and maintain the safety of current arrangements. However, does the Minister agree that, for all sorts of reasons, there is a danger of a combination of factors leading to a no-deal situation by default, even though a majority of Members claim they do not want that?

The answer to all this is for people to work together across parties for a satisfactory deal, to ensure that we give certainty to businesses and those in public policy areas—particularly social and health policy—that when we reach the end of March there will be a transition period in which more detail on other arrangements can be sorted out, and to allay people's fears about falling off a cliff edge. It seems to me that there was cross-party support for that—in fact, my party argued for a transition period and many Members, including some of my colleagues here today, also argued for avoiding a cliff edge.

As someone who is on the organ donor register and is a blood donor—I hope everyone else in the room is, too—I think it is really important that we address the positive here. As we leave the European Union, we should get a positive deal that asserts our independence but recognises that, in areas such as this, working across 28 nations within the EU, we have developed some law that we want to continue, regardless of whether we are in or not.

9.16 am

Jackie Doyle-Price: It is a pleasure to follow the right hon. Member for Don Valley. I do not think I disagreed with a word she said. I recognise that, for some Members, it is a matter of regret that we are leaving the European Union. None the less, we are committed to delivering the instruction given by the British people in the referendum. I think I speak for most people in the room when I say we would prefer to do that on the basis of an agreed deal with our European allies, but we need to be ready for the eventuality that we are not able to secure such a deal. That is why we introduced these SIs. I am grateful to Committee members for their pertinent questions. They are evidence—if only the public could see it—of how seriously we are taking the challenges of a no-deal Brexit, which of course we all wish to avoid as best we can.

A number of Members expressed concerns about whether affected establishments had been properly communicated with and were ready for the changes in these regulations, and about costs. We issued a technical notice to all affected parties in August to give them due

notice to be able to prepare for the regulations. As was referred to, there is a six-month implementation period, but we expect that preparation to have been undertaken now. Given that it effectively will be business as usual, we expect that preparation to be relatively straightforward. Some of the things we have put in, such as the six-month transition period, are really just a sort of legal process to set deadlines, but we expect all those affected to be compliant almost immediately.

On the issue referred to in the technical notice of whether establishments might need to seek separate advice, we expect establishments just to engage with the regulators. Again, this will be business as usual, but the regulators stand ready to give all those affected as much advice as they need to be able to comply.

The hon. Member for Gedling is quite right that the updated information was not published in November, but it has now been published. It was published on 7 December, so it was slightly delayed—that is not unusual when it comes to things associated with Brexit—but it can be found online, and I will draw his attention to it.

Vernon Coaker: Google couldn't find it.

Jackie Doyle-Price: Google has its limitations, it has to be said.

On whether costs need to be reimbursed, it is worth noting that we expect the costs incurred by establishments to be extremely low. The main impact of the draft regulations relates to agreements that establishments have to put in place with whomever they trade with, but most establishments already hold import licences and are well used to making and applying such agreements. We expect them simply to roll over their existing written agreements. Again, however, NHSBT and the Human Tissue Authority will work with and support establishments to put those agreements in place. There will be no impact on organ transplant centres, and in the case of non-reproductive cells we think all the establishments concerned will already have such agreements in place. On that basis, we do not expect any establishment to incur significant costs, so there will be no need for any reimbursement.

The right hon. Member for Don Valley and the hon. Member for Washington and Sunderland West mentioned organ donation. Clearly, the 30 organs that come in and out of the country every year are a matter of life and death. It is of considerable concern to me that we have sufficient provision in place to ensure that that can continue. Much of that movement is between the Republic of Ireland and the north, and at this stage we do not anticipate significant problems there, but there is good reason to worry about Dover-Calais.

We have all heard the concerns about whether things will be able to get into the UK through that entry point. We are working with the Department for Transport to ensure that things such as medical supplies, including organs, can get through if there is traffic congestion. We are making such provisions—contingency plans will be in place. I hope we do not get to the point of having no deal, but we are determined to ensure as best we can that, if we do, it will be business as usual and that, for example, couriers are escorted so they can navigate traffic more quickly. It is very much on our agenda to ensure that we can enable that to happen.

Question put and agreed to.

DRAFT QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2019

Resolved,

That the Committee has considered the draft Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019.—*(Jackie Doyle-Price.)*

DRAFT HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019

Resolved,

That the Committee has considered the draft Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019.—*(Jackie Doyle-Price.)*

9.24 am

Committee rose.