PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Fifth Delegated Legislation Committee

DRAFT BLOOD SAFETY AND QUALITY (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: Mr Virendra Sharma

† Brine, Steve *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Cartlidge, James *(South Suffolk)* (Con)
† Churchill, Jo *(Bury St Edmunds)* (Con)
Cunningham, Alex *(Stockton North)* (Lab)
† Docherty, Leo *(Aldershot)* (Con)
† Efford, Clive *(Eltham)* (Lab)
† Elmore, Chris *(Ogmore)* (Lab)
† Hodgson, Mrs Sharon *(Washington and Sunderland West)* (Lab)
† Johnson, Dr Caroline *(Sleaford and North Hykeham)* (Con)
† Jones, Mr Kevan *(North Durham)* (Lab)
† Lefroy, Jeremy *(Stafford)* (Con)
† Moore, Damien *(Southport)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Rimmer, Ms Marie *(St Helens South and Whiston)* (Lab)
† Throup, Maggie *(Erewash)* (Con)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)
† Wood, Mike *(Dudley South)* (Con)

Rob Cope, Kevin Candy, *Committee Clerks*

† attended the Committee

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[Mr Virendra Sharma *in the Chair*]

Draft Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019

2.30 pm

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

That the Committee has considered the draft Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019.

It is nice to see you, Mr Sharma.

The draft regulations are made under powers in the European Union (Withdrawal) Act 2018 to make the necessary amendments to the UK's Blood Safety and Quality Regulations 2005. The instrument will correct those regulations to ensure that the UK is prepared in the unlikely event that it leaves the EU without a deal on 29 March next year.

The UK regulations set out the safety and quality requirements that cover all steps in the blood transfusion process from donation, collection, testing, processing and storage to distribution. The short shelf life of such products means that an uninterrupted process of donation and processing is needed to ensure that the UK has a safe continuity of supply for blood and blood components. Patients rely on the treatments every day, and many people would not be alive today if it were not for the generosity of blood donors—I want to place that on the record.

As a responsible Government, we have been preparing for all scenarios, including that we leave the EU without a deal in March. The draft statutory instrument will ensure that the regulatory regime for blood safety and quality continues to function effectively after exit day. It is important to make the changes for the continued donation and processing of blood and blood components such as plasma and platelets to facilitate a wide range of essential and often life-saving treatment. In addition, the donated plasma is a component of blood that can be used to manufacture medicinal products such as clotting factors and immunoglobulins.

To be clear, the instrument is limited to the necessary technical amendments to ensure that legislation is operative on EU exit day. It confers powers—from the EU Commission to the Secretary of State—to make the technical changes. However, no policy changes are made through the draft regulations, and at this point we have no intention of making any. I commend the regulations to the Committee.

2.33 pm

Mrs Sharon Hodgson (Washington and Sunderland West) (Lab): It is a pleasure to serve under your chairmanship, Mr Sharma, and to be in Committee on another SI. We were at it this morning and yesterday, if not with this Minister, with his colleague. A few in the room, such as his Parliamentary Private Secretary and our team's PPS, are seemingly doing both, or all, stints. We were at it yesterday as well. I understand that a few SIs are going on across the Committee Rooms at the moment.

As I said this morning, I would prefer that we did not have to do any SIs because we are leaving with a deal and do not have to worry about no deal. As a matter of contingency planning, however, it is only right to be in Committee to discuss the changes as a just-in-case measure.

Having said that, people will be rightly concerned that we are even having to make contingency plans in the event that we have a no-deal Brexit, so what assurances will the Minister give patients, in particular those with rare diseases who receive important blood and blood components? Will the Minister give assurances that the changes will not affect the safety, quality or supply of blood and blood components in the UK, and that the standards we enjoy now will be maintained? The UK has set the regulatory benchmark for the EU, so it is important that that is not impaired post Brexit.

I understand that regulation 8 means that a UK establishment, rather than an EU establishment, will be responsible for labelling, recording and storing blood from the EU. Will the Minister confirm that the UK has the capacity to label, record and store blood, and which UK establishment will be responsible?

I hope the amendments will not be needed in the end, but I appreciate that the Government have to make them and are keen to get it right. I therefore hope the Minister will consider everything that has been mentioned and will give us assurances.

2.35 pm

Dr Philippa Whitford (Central Ayrshire) (SNP): All of us with constituents who have suffered under the contaminated blood scandal recognise the absolute importance of maintaining the standard of blood for transfusion, as well as other donated tissues and organs. I welcome the draft regulations and that we will maintain the standard. The issue will be in paragraph 7.12 of the explanatory memorandum on technical updates under article 29: as technology develops and issues arise, will we continue to match that standard? The hon. Member for Washington and Sunderland West asked who in the UK will take on that responsibility.

I notice in section 7.3 of the explanatory memorandum that approximately 6.5% of plasma is imported from the EU, although the UK is largely self-sufficient in blood itself. I take the opportunity to remind people, whether or not they are blood donors, that there is still time to donate a wee pint of blood before we go into Christmas. As a surgeon I can say that we always run out or come close to running out. There is still time to save a life. How will we compensate for that 6.5% of plasma that we import for direct clotting factors and immunoglobulins, to which the Minister referred?

The explanatory memorandum states that there will no longer be an obligation on UK authorities to report serious adverse effects. Although I understand there would not be an obligation once we are outside the EU, I would have thought it was still good practice to share information on serious adverse effects that have occurred here and that might occur elsewhere in Europe and,

similarly, to encourage the sharing of information so that if there is an adverse event, we are given that information in return.

I am slightly surprised that, in section 7.9 of the explanatory memorandum, Gibraltar is defined as a third country—it defines EU member states as third countries, but also Gibraltar. I am a little confused about why it would be considered a third country.

I welcome the draft regulations in general, but there seem to be a few little threads hanging. I would be grateful if the Minister could give us comfort on those or further information either from reviewing it or by sending it to us later.

2.38 pm

Jeremy Lefroy (Stafford) (Con): The hon. Member for Central Ayrshire made both the points I intended to make. Very briefly, the situation of Gibraltar as a third country strikes me as very odd. On the obligation for the maintenance of communication of serious adverse events, although I understand that it should no longer be an obligation, it should still have to happen. It is absolutely vital that that takes place. Will the Minister say how he intends to ensure that it will?

Finally, I refer to something that I often speak about in the context of the very sad case of our leaving the European Union: the importance of maintaining research across borders of blood diseases and all kinds of health problems we are tackling, because they know no borders. We have to continue and strengthen that. Could the Minister briefly comment on that in the context of these draft regulations?

2.39 pm

Clive Efford (Eltham) (Lab): It is a pleasure to serve under your chairmanship, Mr Sharma. I have a couple of brief questions of the Minister.

First and foremost, the point that has to be made about this scenario is that there is no majority in the House of Commons for us to leave with no deal. That needs to be underlined. If we do leave without a deal, it will be entirely the fault of the Prime Minister.

That aside, what implications does this treatment of the UK as a third country by the European Union have down the road? Has the Minister considered that? What about continued supply? Are we in competition with other European countries? Is supply likely to be interfered with? Will priority be given to EU countries over us for that supply? I might be worrying unnecessarily, but I would like to know whether the Minister has given that any consideration, or whether it is in fact the case.

Similarly, on future improvements in standards, technology and knowledge, will we keep up under article 29 with technical improvements in the field? Will we mirror that in this country? How will we keep ourselves at the forefront of medicine in this area to ensure that we do not fall behind our European neighbours as a consequence of not being part of the collective that deals with such issues under article 29 of the European treaty?

2.41 pm

Steve Brine: The hon. Member for Washington and Sunderland West, my shadow from the Labour party, talked about regulation 8. Each blood establishment will be responsible for the labelling, storage and so on of blood. There is no change; the only change to regulation 8 is from "European Union" to "third country", which of course is what we would become in the event that that happened. We have made sure that the UK blood establishments have capacity for labelling.

The hon. Lady also asked about patient safety. The statutory instrument will ensure that the existing high standards of safety and quality of blood and blood components is continued. There is no increased risk to patient safety.

The hon. Lady and the hon. Member for Eltham both talked about supply. The draft regulations will not affect the supply of blood or blood components in the UK. As the hon. Member for Central Ayrshire from the Scottish National party said, the UK is largely self-sufficient in blood and blood components. We do not routinely import or export blood components.

One exception to that is blood plasma—we import about 6.5% of our total blood plasma units from the EU, as has been said, as a safety measure against BSE for people born after 1996. We are putting contingency plans in place to ensure a continuing safe supply after 29 March. NHS Blood and Transplant will be stockpiling plasma centrally to ensure continuity of supply.

The hon. Member for Central Ayrshire is absolutely right about the importance of that in ongoing medicine and in keeping people safe, which is why I feel confident in saying that there will be no adverse impact on patient safety as a result. That involves fast-tracking shipments at ports and alternative routes being prepared, while partners stockpile alternative medicinal products and consumables.

The hon. Member for Washington and Sunderland West talked about regulatory benchmarks. She is absolutely right to say that that is our work—we have been a member state for 40 years, and we have no intention of diverging from that, because we wrote most of it. One of the reasons why, through this SI, we are updating the powers to give the Secretary of State power to amend the regulations is so that, on exit day—if that happens as we hope it will not happen—we would be in exactly the same place.

Obviously, if the ongoing review in the European Union 27 of the future of blood and blood component products decides to make changes, we would also be in the position of being nimble enough to make changes ourselves to ensure that we stay close to them in a regulatory benchmark way. My views on EU exit are well known, but I do not think anyone voted in order to diverge from our closest partners on blood supply.

Gibraltar is making its own EU exit legislation. The Gibraltar Government have been closely engaged with the Department, and we with them. Gibraltar meets the same standards as the UK, and I see no reason for that not to continue.

On the devolved Administrations, because blood is a devolved competence, the SI confers the EU Commission's regulation-making powers on to the Secretary of State and on the relevant DAs, with the devolved Administration's consent. We are engaging with the blood establishments, the Medicines and Healthcare products Regulatory Agency and the DAs to ensure that there is day-one operability for blood safety and quality legislation.

Scotland, Wales and Northern Ireland—dealing with the civil service in the latter—have provided their consent for this instrument, and they have been closely involved in its development over the past six months. I place on

[Steve Brine]

record my thanks to those in Scotland and Wales, and the civil servants in Northern Ireland, who have worked well and closely with us to ensure that this is done safely and sensibly.

In answer to a point made by the hon. Member for Eltham, we will go all out to ensure that we do not need the draft regulations. Dare I say it? The best way to avoid no deal is to have a deal, and Members will get the opportunity to agree one when we come back in the new year.

Question put and agreed to.

2.46 pm

Committee rose.