PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

First Delegated Legislation Committee

DRAFT MEDICAL DEVICES AND BLOOD SAFETY AND QUALITY (FEES AMENDMENT) REGULATIONS 2023

Monday 6 March 2023

No proofs can be supplied. Corrections that Members suggest for the final version of the report should be clearly marked in a copy of the report—not telephoned—and must be received in the Editor's Room, House of Commons,

not later than

Friday 10 March 2023

The Committee consisted of the following Members:

Chair: Sir George Howarth

† Atherton, Sarah *(Wrexham)* (Con)
† Baker, Duncan *(North Norfolk)* (Con)
† Browne, Anthony *(South Cambridgeshire)* (Con)
† Clark, Feryal *(Enfield North)* (Lab)
† Day, Martyn *(Linlithgow and East Falkirk)* (SNP)
Foy, Mary Kelly *(City of Durham)* (Lab)
Gardiner, Barry *(Brent North)* (Lab)
Greenwood, Margaret *(Wirral West)* (Lab)
Hardy, Emma *(Kingston upon Hull West and Hessle)* (Lab)
† Henderson, Gordon *(Sittingbourne and Sheppey)* (Con)
† Jones, Fay *(Brecon and Radnorshire)* (Con)
† Moore, Damien *(Southport)* (Con)
† Quince, Will *(Minister for Health and Secondary Care)*
† Simmonds, David *(Ruislip, Northwood and Pinner)* (Con)
† Wakeford, Christian *(Bury South)* (Lab)
† Wheeler, Mrs Heather *(South Derbyshire)* (Con)
† Whittingdale, Sir John *(Maldon)* (Con)

Liam Laurence Smyth, *Committee Clerk*

† attended the Committee

First Delegated Legislation Committee

Monday 6 March 2023

[Sir George Howarth *in the Chair*]

Draft Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023

4.30 pm

The Minister for Health and Secondary Care (Will Quince): I beg to move,

That the Committee has considered the draft Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023.

It is a pleasure to serve under your chairmanship, Sir George. I am grateful to be here to debate these important regulations. The purpose of the provisions is to update the fees payable to the Medicines and Healthcare products Regulatory Agency in relation to its regulation of medical devices and blood components for transfusion.

As is standard practice for Government bodies that charge fees, the MHRA's fees have been updated several times in the past to ensure they remain appropriate. However, to provide certainty and stability to the sector throughout the EU exit transition period and, of course, the covid-19 pandemic, the MHRA has not updated its fees since the financial year 2017-18 for medical devices and the financial year 2010-11 for blood components for transfusion. It is not sustainable for the MHRA to continue charging fees at their current level, as they do not adequately recover the costs involved in delivering those crucial regulatory services.

This statutory instrument therefore introduces amendments that fall into three categories. First, there is a 10% indexation increase on all fees. The indexation is simply linked to MHRA staff costs, which, in line with the wider civil service pay award, have risen by 10% since the last substantial MHRA fee increases in 2016. Secondly, there is a further uplift for a specific number of activities identified as significantly under-recovering via their fees to ensure cost recovery. Thirdly, there is the introduction of new fees for services that require cost recovery since the last fee changes in 2018 for medical devices.

The SI also introduces two new optional services related to clinical investigations of medical devices that industry may take advantage of. These services relate to obtaining expert regulatory advice or statistical reviews from the MHRA in relation to clinical investigation of a medical device. The changes are necessary because the MHRA is obliged to recover the costs of its regulatory activities in accordance with the Treasury's "Managing Public Money" guidelines.

The SI amends a range of fees for the MHRA's medical devices and blood components regulatory work to ensure that the MHRA recovers its costs associated with delivering those crucial services. This full cost recovery approach means that the regulated bear the cost of regulation and the MHRA does not profit from fees at the expense of industry—nor, importantly, does the MHRA make a loss that would fall on UK taxpayers and patients to subsidise.

The fees updates are important to ensure that the MHRA has the resources it needs to deliver a reliable service. The updates will in turn contribute to operating modernised systems and processes, to the recruitment and retention of skilled staff, and to keeping pace with technological advancements. They will support the delivery of a responsive and efficient regulatory service that protects and improves public health.

The MHRA is committed to regularly reviewing its fees, ensuring that they remain fair and reasonable and continue to reflect the true cost of providing regulatory services. By supporting the regulations, we help to ensure that the agency is financially sustainable and sufficiently resourced to provide its essential services more consistently, and so to provide patients, the public and industry with the level of service they expect. I commend the regulations to the Committee.

4.34 pm

Feryal Clark (Enfield North) (Lab): It is a pleasure to serve under your chairmanship, Sir George.

As has been said, the SI serves to allow the MHRA to increase the fees it charges for regulating medicines and related products. Of course, any steps the Government take to ensure that the MHRA can carry out its role more effectively are to be welcomed.

The SI will introduce a 10% increase in all the MHRA's statutory fees, and an above 10% increase for 61 services that have seen costs grow significantly. Furthermore, it will introduce 22 new fees to ensure that the MHRA adequately recovers the costs of regulatory activity across all its services, in line with His Majesty's Treasury principles on managing public money.

I understand and appreciate that the MHRA has not increased its fees to this extent since 2016-17, to provide the industry with certainty and stability through the EU exit period and the covid-19 challenges. I am pleased that the MHRA has gone through the consultation process to arrive at its judgment, thereby ensuring that the views of relevant stakeholders are reflected. The MHRA needs to be financially stable to be able to deliver regulatory services that protect and improve patient safety, with high-quality, safe, effective and innovative medical products, and any steps that the Government take to address that are of course to be welcomed.

We appreciate the greater clarity that the SI provides on the increased costs of providing quality care in our health services. However, I am concerned about where the increased costs of the fees will be absorbed. They simply cannot be absorbed by the NHS, which is already facing the worst crisis we have ever seen. I would therefore appreciate it if the Minister could outline how the Government will ensure that the increase in costs is not absorbed by the NHS.

We are always looking to make further strides in patient safety, and we are confident that the SI takes that into account. I look forward to hearing the Minister's response to some of the points I have made.

4.37 pm

Anthony Browne (South Cambridgeshire) (Con): I want to say a few words, because, as the Minister is well aware, I am the MP for South Cambridgeshire, which is the life sciences capital of the UK, with 400 life sciences

companies. Some of the feedback I have had about the MHRA suggests that it is under-resourced, so I very much welcome this increase in its resourcing. A lot of companies in my constituency are doing a lot of innovation, and they say that one of the constraints on them is getting their work through the MHRA and its ability to process it. I was glad to hear the Minister say that the regulations will help the MHRA keep up with innovation, hire new staff and so on.

How do we make sure that we do not get in this position again? Can the Minister indicate how we will make sure that the MHRA stays up to speed and is able to cope with new innovation in the future? I do not expect him to announce future fee increases now, but can he give us a sense of direction? In addition, what does the Department do to hold the MHRA to account? Does it scrutinise how quickly it works with industry and so on to deliver its services?

4.38 pm

Will Quince: I thank the hon. Member for Enfield North for her broad support and for her comments regarding the fees. The fee updates are important to ensure that the MHRA has the resources it needs to deliver a reliable service. The extra £1.9 million that we anticipate being raised will go directly to support the MHRA's ability to operate modernised systems and processes, to recruit and retain skilled staff, and to keep pace with technological advancements. That £1.9 million is to support the MHRA in cost recovery; it is not to go to the broader NHS.

My hon. Friend the Member for South Cambridgeshire rightly touched on whether this is a temporary measure. It is not; we intend now to get back to business as usual. There was a temporary measure in place because of EU exit and covid, and the pressures on the MHRA and industry. We removed that. This is catch-up, and the plan will be to get back to business as usual.

On scrutiny of the MHRA, I meet regularly with its chief executive—and others, because, as my hon. Friend knows, it is a holistic environment. We have to ensure that the MHRA is working closely with the National Institute for Health and Care Excellence, industry, charities and, of course, the NHS and the Department of Health and Social Care, to ensure that we create a competitive environment in which businesses want to conduct clinical trials and to invest and bring forward innovation in medtech here in the United Kingdom.

To my hon. Friend's direct point, beyond this measure, the MHRA has delivered an ambitious transformation programme and put in place a new organisational structure with a clear mission for oversight of healthcare products. That goes all the way from first discovery through to deployment. Work is under way on optimising the services offered and developing new services. That is very much supported by a substantial technology investment programme, which includes upgrading support systems—replacing things such as the legacy system that the MHRA had before—and investing in new technology.

I hope that answers the questions asked by the hon. Member for Enfield North—I will call her my hon. Friend—and my hon. Friend the Member for South Cambridgeshire. The MHRA provides essential services and plays a crucial public health role. It is absolutely right that it is able to cover its costs to do that, and these fee increases are now necessary. By supporting the regulations, we will ensure that patients, the public and industry are provided with the service that they rightly expect and, in so doing, protect public health and encourage innovation.

Question put and agreed to.

4.41 pm

Committee rose.