PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Second Delegated Legislation Committee

DRAFT MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY TRADING FUND (AMENDMENT) (EU EXIT) ORDER 2018

Thursday 11 October 2018

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not later than

Monday 15 October 2018

The Committee consisted of the following Members:

Chair: Mr Adrian Bailey

† Brine, Steve *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Davies, Chris *(Brecon and Radnorshire)* (Con)
Evans, Chris *(Islwyn)* (Lab/Co-op)
† Hands, Greg *(Chelsea and Fulham)* (Con)
† Hill, Mike *(Hartlepool)* (Lab)
† Kawczynski, Daniel *(Shrewsbury and Atcham)* (Con)
† Latham, Mrs Pauline *(Mid Derbyshire)* (Con)
Lucas, Ian C. *(Wrexham)* (Lab)
† Madders, Justin *(Ellesmere Port and Neston)* (Lab)
† Menzies, Mark *(Fylde)* (Con)
† Morris, James *(Halesowen and Rowley Regis)* (Con)
† Morton, Wendy *(Aldridge-Brownhills)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Peacock, Stephanie *(Barnsley East)* (Lab)
Pearce, Teresa *(Erith and Thamesmead)* (Lab)
† Throup, Maggie *(Erewash)* (Con)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)

Yohanna Sallberg, Hannah Bryce, *Committee Clerks*

† attended the Committee

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[Mr Adrian Bailey *in the Chair*]

Draft Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) (EU Exit) Order 2018

11.30 am

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

That the Committee has considered the draft Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) (EU Exit) Order 2018.

It is a pleasure to see you in the Chair, Mr Bailey, and to see other Committee members present. I look forward to spending the rest of the day with them. *[Laughter.]* I do not see why that is funny.

The Medicines and Healthcare Products Regulatory Agency regulates medicines, medical devices and blood components in the UK on behalf of my right hon. Friend the Secretary of State for Health and Social Care. It is financed by a trading fund established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, which was made under the Government Trading Funds Act 1973. The Act introduced trading funds as a means of financing the revenue-generating operations of Departments, which had previously been financed through the Supply process. A trading fund operates outside that process and has standing authority to meet all outgoings from its receipts. Operations financed by a trading fund must be managed so that the fund's revenue is sufficient to meet its expenditure on them.

Schedule 1 to the 2003 order sets out the MHRA's funded operations—the operations that it can fund using the revenue that it generates from them. In places, the schedule identifies them with cross-references to specified EU legislation. The draft order's primary purpose is to remove those cross-references prior to the UK's withdrawal from the European Union, so that the MHRA trading fund remains fully operational after that time. We would not have detained the Committee today if that had not been necessary, but since it was, we have also taken the opportunity to set out the MHRA activities covered by the trading fund in a clearer and more transparent way.

The changes that the draft order will make are purely administrative; they will not alter the activities that can be carried out by the MHRA under its trading fund. The agency does not seek to carry out any new activity on the basis of them, nor will they enable it to introduce new fees that it could not otherwise introduce. No impacts on third parties will result from the draft order. It has been drafted so that the trading fund will work regardless of the outcome of the EU exit negotiations. We therefore see no reason to delay making these changes, which will also bring greater clarity and transparency, so the draft order is scheduled to come into force the day after it is made.

The draft order makes a simple, but necessary, administrative change. I commend it to the Committee.

11.33 am

Justin Madders (Ellesmere Port and Neston) (Lab): It is a pleasure to serve under your chairmanship, Mr Bailey. As the Minister said, there is little in the draft order that is controversial; the changes it makes are of a technical nature and are necessary as we approach Brexit.

Of course, there is much wider controversy about Brexit as a whole, and—in the context of this debate—particularly about its impact on the British pharmaceutical industry. I do not believe that anyone voted to make the national health service worse off; indeed, the bus advertisements would have led people to think that they were voting for the contrary. However, the decision to leave the European Medicines Agency could have far-reaching consequences, which is why the head of the Association of the British Pharmaceutical Industry recently stated that we are seeing a British success story being broken up. Until the decision was taken, the EMA headquarters in London had approximately 900 high-quality jobs. The MHRA also played a leading role in the EMA authorisations process.

In 2016, the UK was the rapporteur on 22 applications for new medicines and co-rapporteur on a further 19. That represented 36% of the total number of applications. This year, with a much different environment envisaged, the MHRA bid for 36 contracts, but was awarded only two. Of course, there will be no more contracts in the future.

Will the Minister explain what impact the loss of contracts will have on the MHRA? Will there be any shortfall, and can the Minister confirm that any shortfall will not be made up from existing NHS budgets? As we know, the life sciences sector in our country has a turnover of more than £60 billion a year, generates exports worth £30 billion and has a trade surplus of over £3 billion per annum. It employs 220,000 people, and 25% of the world's top prescription medicines were discovered and developed in the United Kingdom.

The north-west, where my constituency is based, is one of the leading regions of the country for pharmaceuticals, employing about 18% of the total national workforce. Projects such as the proposed Cheshire science corridor are a really important factor in that. Can the Minister indicate what he thinks the likely impact of the decision to leave the EMA will be on the sector as a whole, and what steps he is taking to minimise that? There are also potential effects on patients' access to new medicines and treatments.

The Office of Health Economics has warned that the average likely submission for marketing authorisation in the UK could take up to three months, that up to 15% of applications could be submitted more than a year after an European economic area submission, and that some products may not be tested or marketed in the UK at all. The OHE also found that 45% of applications were not submitted to Australia, Canada or Switzerland following submission to the EMA. Can the Minister give us assurances on the risks to the general availability of prescriptions and medicines for patients?

We do not oppose these regulations, but there are much wider and more profound questions about the Government's attitude towards medicine regulation in this country. I hope the Minister can reassure us that the Department is stepping up to that particular challenge.

11.37 am

Dr Philippa Whitford (Central Ayrshire) (SNP): I, too, have a life sciences park in my constituency. Regardless of whether Members have them in their constituency, drug access is of course critical to all our patients. The EMA has made a huge difference in the access to drugs: the speed at which they leave the bench, are developed and arrive in doctor's surgeries or the NHS. If we look at Canada and Australia, we see that the delay is between six months and a year.

The problem is that the MHRA can be strengthened by itself, but that does not replace collaboration. It is not a matter of going into one's own little corner and having more money or equipment if collaboration is not possible. As well as licensing, the EMA has driven research, particularly on rare or congenital conditions such as childhood cancers. We have made huge progress on these conditions in the last decade—much better than in several decades previously.

My party, too, does not object to the fine print of this legislation, but it does not sit by itself. Our concerns are about how it fits in the wider context, what support will be provided to the MHRA and how exactly it plans to bring drugs on, because it can still take quite a considerable time for new drugs—between licensing through the EMA and within the UK—to be routinely available through the NHS. I am hearing from pharmaceutical companies that it will not take three months, six months or a year. They feel that, when a drug is expensive, it will not be used by the NHS. What is the point in their paying to go through a separate, expensive process, if it will be another three years before the drug is likely to be commonly used? We could therefore see considerable delays, and, if the drug is not licensed in this country, it will not be something that doctors can prescribe as an exception, or that the National Institute for Health and Care Excellence or the Scottish Medicines Consortium can recommend. That will put us way behind: if we are not using what is recognised as current gold standard, we cannot take part in gold standard new drug trials. Therefore, having been a major player in medical—particularly pharmaceutical—research across Europe, the UK could fall a long way behind.

I also want to ask quite a simple question, because the Minister said that the MHRA is able and expected to use those trading funds to fund all its operations. As the hon. Member for Ellesmere Port and Neston pointed out, having bid for 36 rapporteur contracts this year, the MHRA was awarded only two, because it was felt that it could not guarantee completing them before 29 March 2019. That means that there will be a huge drop in income for the MHRA, which will not only have to carry out the investigations it has done in the past—between 25% and 35% of EMA work—but will have to go through a duplicate process for the UK. Do the Government envisage—if there are no new activities and no rise in fees—a return to a Supply process in which they fund the MHRA? The order does not specify how the MHRA will be funded.

11.41 am

Steve Brine: There are lots of wider points, but we have gone off-topic. The order is very specific and seeks to make sure that the agency can still function after Brexit, regardless of the deal or no-deal scenario. The shadow Minister, the hon. Member for Ellesmere Port and Neston, asked about the impact on the NHS and on NHS funds. As I have said, the MHRA is self-funding, and this will not impact the NHS at all. It is not as if the MHRA is going to come and ask for its slice of the £20.5 billion extra funding that we will be giving the NHS every year from next year as a result of the new funding settlement in the long-term plan.

It is self-evident that we cannot have the vast significant change of leaving the European Union without there being a change in our relationship, but as we have made very clear—the Prime Minister made it very clear in her Lancaster House speech and subsequently—the UK is seeking active participation in the EMA, as part of the future economic partnership. That is still very much subject to negotiations, but it is where we want to get to.

As a trading fund, the MHRA is required to cover its costs by charging for its work. The hon. Member for Ellesmere Port and Neston therefore asks an important question, but as part of the Brexit contingency planning, the agency is working in conjunction with the Government and the Department to ensure that it has a balanced budget post-Brexit, irrespective of the outcome. The majority of its licensing activity and the associated income derive from domestic—national, not EU—licensing.

The future trading relationships for the agency were outlined as part of our no-deal preparation planning. On 4 October, the MHRA opened a consultation on EU exit no-deal listed proposals. That is a live consultation which seeks views on how the agency's legislation and regulatory processes would have to be modified in the event of the UK not securing a deal, and it covers no-deal proposals on medicines, clinical trials and medical devices. That live consultation closes at quarter to midnight on 1 November, so it would not be appropriate for me to pre-empt what it will say, but I am not concerned that the MHRA will raid NHS funds. Of course there are concerns—and we share them—about the change in relationship, but the UK has made clear that it seeks a new relationship, one of associate membership and creative partnership, with the EMA, as part of the future economic partnership.

Dr Whitford: I thank the Minister for giving way. I am sure that he is well aware that no "associate membership" of the EMA exists. It is one of the agencies that simply does not have any opportunity for associate membership, so expecting it to set up an entirely new structure for a member that is leaving seems over-hopeful. The Minister is still talking about no new activities and no rise in fees. It is still hard to understand, particularly if the consultation is still open, how he is able to give that guarantee and yet tell us how the MHRA will have funding to go forward.

Steve Brine: I am not giving the hon. Lady that guarantee. I am saying that it is a live consultation and it would not be appropriate for me to pre-empt it. I do not share the hon. Lady's half-full view of our ambition for the future, which the Prime Minister set out in terms of our relationship with the EMA. The EU does not have a relationship with the UK as a third country at the moment. That is why we have set out an ambitious proposal for our new relationship with the EU and its agencies, including the EMA. I am hopeful, as are the Prime Minister and the Government whom I speak on

[Steve Brine]

behalf of, that we will secure a good deal. We still think that that is the most likely outcome. That includes a new relationship with the EMA. We should remember that the expertise that we have in this country, and the work we do with the EMA, will not suddenly change because it is based in Amsterdam. It will still need that expertise and that relationship. I am ambitious about the future, which is why I say what I say.

The matter before the Committee today is technical, to make changes to enable the agency to function after exit day.

Justin Madders: The Minister is speaking with great confidence, without any basis in fact, in saying that the MHRA will not need any state handouts in the future. Will he commit to report back to Parliament, if it turns out that it is not, in future, self-financing?

Steve Brine: Of course, if there is any change to any arm's length agency that the Department works with, we will come back to Parliament for that discussion. That is partly what the consultation is about at the moment. So if the hon. Gentleman wants a blank cheque to say that we would come back to the House to have discussions around any future changes, the answer is self-evidently yes.

Question put and agreed to.

11.47 am

Committee rose.