PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

First Delegated Legislation Committee

DRAFT MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY TRADING FUND (AMENDMENT) ORDER 2016

Monday 25 April 2016

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not later than

Friday 29 April 2016

The Committee consisted of the following Members:

Chair: Mr Andrew Turner

† Argar, Edward *(Charnwood)* (Con)
† Berry, James *(Kingston and Surbiton)* (Con)
† Burns, Sir Simon *(Chelmsford)* (Con)
† Flynn, Paul *(Newport West)* (Lab)
† Freeman, George *(Parliamentary Under-Secretary of State for Life Sciences)*
† Fysh, Marcus *(Yeovil)* (Con)
† Garnier, Mark *(Wyre Forest)* (Con)
Godsiff, Mr Roger *(Birmingham, Hall Green)* (Lab)
† Kirby, Simon *(Brighton, Kemptown)* (Con)
† Lord, Jonathan *(Woking)* (Con)
† Lynch, Holly *(Halifax)* (Lab)
† Mactaggart, Fiona *(Slough)* (Lab)
† Madders, Justin *(Ellesmere Port and Neston)* (Lab)
Mullin, Roger *(Kirkcaldy and Cowdenbeath)* (SNP)
† Phillips, Stephen *(Sleaford and North Hykeham)* (Con)
† Streeting, Wes *(Ilford North)* (Lab)
Tyrie, Mr Andrew *(Chichester)* (Con)

Helen Finlayson, *Committee Clerk*

† attended the Committee

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[Mr Andrew Turner *in the Chair*]

Draft Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2016

4.30 pm

The Parliamentary Under-Secretary of State for Life Sciences (George Freeman): I beg to move,

That the Committee has considered the draft Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2016.

This technical amendment allows the Medicines and Healthcare Products Regulatory Agency to fund its work on e-cigarettes through fee income. The implementation of the tobacco products directive and the specific fee regime to cover regulatory activity undertaken by the MHRA are covered in separate legislation that has been laid before Parliament. The order affects only the MHRA, as it changes very slightly the terms on which the MHRA operates as a trading fund. As an accounting change, it is debated in the House of Commons, but not the House of Lords.

As I said, the fees themselves are the subject of separate legislation. However, the proposed fee levels for the coming year are £150 to notify a new product, £80 to notify a substantial modification to an existing product and a £60 annual fee per notified product starting from 1 April 2017. The fees are set at a level that will enable the MHRA to recover the cost of reviewing information on new products notified through the EU portal and of carrying out subsequent publishing and monitoring work. The fee levels will be reviewed during the first year and regularly thereafter in consultation with the e-cigarette industry, health advisory bodies and the public to ensure that they remain a proportionate and fair recovery of the cost of undertaking that work.

4.32 pm

Justin Madders (Ellesmere Port and Neston) (Lab): It is a pleasure to serve under your chairmanship, Mr Turner. I noticed that the Minister was slightly breathless. I am sure that that has something to do with his exertions yesterday, on which I congratulate him.

The Opposition support the order. We recognise that the technical amendments proposed for the MHRA are required to deal with the regulation of electronic cigarettes, particularly in respect of the revised tobacco products directive.

Despite the continuing long-term decline in the number of smokers over the past few decades, the latest estimates suggest that there are more than 100,000 smoking-related deaths each year, and Action on Smoking and Health has estimated that the cost to the NHS of smoking is between £2.7 billion and £5.2 billion a year.

In August 2015, Public Health England published evidence indicating that e-cigarettes are "95% safer than smoking", pose

"no risk of nicotine poisoning"

and release "negligible" amounts of nicotine into the environment. The limited research that has been undertaken so far suggests that these products have a role to play in helping smoking cessation. They therefore need to be licensed by the MHRA to allow them to be sold officially as an aid to cease smoking and prescribed by the NHS. It is also important that regulations are in place to ensure that the products meet quality and safety standards.

In July 2015, the Government held a public consultation on implementing the revised tobacco products directive. We welcome the approach that has been adopted following the consultation, including the requirement for e-cigarette manufacturers to submit information to the Government about every product they sell, the requirement for health warnings on packages and the maximum cartridge size of 2 ml. It is also important that manufacturers that wish to supply their products without a medicinal licence will not be permitted to advertise them as an aid to smoking cessation. It should be noted that the regulation is supported by stakeholders such as Action on Smoking and Health, the British Medical Association and the Royal College of Physicians.

We welcome the order, but I have some questions that I hope the Minister will address when he responds. First, will he comment on the concern of some health stakeholders, which is identified in paragraph 3.16.7 on page 59 of the response to the consultation, that differences in terminology are beginning to emerge between the UK nations? What steps are the Government taking to work with the devolved Administrations to ensure that there is as little confusion as possible? That is particularly important when there are such rapid developments in these products.

Secondly, we support the use of e-cigarettes as an aid for smokers who are trying to quit, but so far the research has been limited. I hope that the commencement of the order will give us an opportunity to undertake larger-scale studies of the effectiveness of e-cigarettes as a smoking cessation tool. Does the Minister intend to review the regulations in this area when more research comes to light? Has there been any assessment of how many patients are likely to be prescribed e-cigarettes? At a time when public health funding is being cut, I am anxious that this should not be seen as a quick fix to plug the gap. Given that the most effective smoking cessation services involve behavioural support in addition to licensed products containing nicotine, it is important that the prescribing of e-cigarettes goes hand in hand with other support and is not seen simply as a replacement for it.

Finally, some health professionals hold that the expansion of e-cigarette use could contribute to smoking becoming normalised again. Does the Minister agree that that is a risk, and what steps is he taking to combat it?

4.35 pm

Paul Flynn (Newport West) (Lab): There is a concern about the operation of the MHRA. The organisation has not been regarded as the ideal body to carry out its functions because it is funded almost entirely by the people it is meant to regulate—the pharmaceutical industry.

There have been serious criticisms concerning the authorisation of a drug called Seroxat, an antidepressant that was found to cause or increase suicides among people who took it in its earliest days. When the MHRA went to investigate, it set up a committee and had to close it down six months later because a majority of its members were employed by the pharmaceutical industry, so the restriction on the use of Seroxat was delayed for a long time.

The main criticism of the organisation is that it is set up to police itself. In other countries, principally Italy, Governments have set up fully independent, free-standing bodies operated by a levy on the pharmaceutical industry, but not controlled by the industry. The MHRA had a chairman who was previously employed by GlaxoSmithKline for many years. Is the Minister happy that this measure is not an extension of that body policing itself and having an interest that is predominantly private and commercial, rather than that of the general public?

4.37 pm

George Freeman: I thank the hon. Member for Ellesmere Port and Neston and the Opposition for their support for the measure, which I expected but which is none the less welcome. It is a sensible piece of legislation, and I am grateful for their support. I will answer the hon. Gentleman's three questions, as well as those of the hon. Member for Newport West.

On terminology, the hon. Member for Ellesmere Port and Neston makes an important point. I am conscious of the need to keep well aligned the devolved Assemblies' different work in this space. As the UK Minister for Life Sciences, I am conscious that the devolved Governments have their own responsibilities, and I have initiated an annual meeting with Ministers from the devolved Administrations to consider the sector. I will table the measure there and raise the point that he has made. I am not aware that it is a problem at the moment, but I think that his point was more about ensuring that it does not become one.

The hon. Gentleman asked about effectiveness. We intend, as part of our more general work on monitoring the effectiveness of the various campaigns against smoking, to ensure that the measure does not have any counter-effect. The Under-Secretary of State for Health, my hon. Friend the Member for Battersea (Jane Ellison), who has responsibility for public health, will lead on that, alongside her work on smoking more generally.

On the hon. Gentleman's third question, I do not fear that the measure might normalise smoking. The evidence that we have received is that it should not, and there is no reason to expect that it will. I agree that we want to ensure that that does not happen.

The charges are not enormous, and they are perfectly in accord with charges across the rest of the medical device sector. For those who wonder what the statutory instrument is all about, it is about ensuring that vaping devices, which contain chemicals and a filament that vaporises liquid to create an inhalant, are properly regulated and monitored, and that the chemical inside is correct.

The hon. Member for Newport West asked whether I am concerned about the danger of the MHRA being distorted by commercial interests. I am not. I am not complacent about it, but wherever I go—in this country, in Europe or around the world—the MHRA is held up as an example of Britain at its absolute best. It is rigorous, it is science and evidence-based, and it is leading the debate on the regulation of 21st-century devices, drugs and diagnostics. In doing that, it is important that it is able to draw on the industry and best practice within it, but, as the Minister with responsibility for the MHRA, I assure Members that in its annual reviews, in my visits and in all my work with it, I see no evidence of undue leniency—if that is the word—with the industry. What I see is an organisation that is committed to regulating in a way that not only ensures that patient safety is paramount, but that helps the industry, on which we all rely for these drugs, devices and diagnostics, to bring them to market. I hope that it is not hostile to industry, but that it is, first and foremost—as, indeed, it is—completely committed to the rigorous implementation of the highest standards of patient safety.

I commend the statutory instrument to the Committee.

Question put and agreed to.

4.41 pm

Committee rose.