PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Second Delegated Legislation Committee

DRAFT PREVENTION OF TRADE DIVERSION (KEY MEDICINES) (EU EXIT) REGULATIONS 2020

Monday 28 September 2020

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not later than

Friday 2 October 2020

The Committee consisted of the following Members:

Chair: Mr Philip Hollobone

Allan, Lucy *(Telford)* (Con)
† Caulfield, Maria *(Lewes)* (Con)
Davison, Dehenna *(Bishop Auckland)* (Con)
Efford, Clive *(Eltham)* (Lab)
† Fletcher, Mark *(Bolsover)* (Con)
† Gibson, Peter *(Darlington)* (Con)
† Largan, Robert *(High Peak)* (Con)
† Nichols, Charlotte *(Warrington North)* (Lab)
† O'Brien, Neil *(Harborough)* (Con)
† Richards, Nicola *(West Bromwich East)* (Con)
† Stuart, Graham *(Parliamentary Under-Secretary of State for International Trade)*
Sultana, Zarah *(Coventry South)* (Lab)
† Thomas, Gareth *(Harrow West)* (Lab/Co-op)
Thompson, Owen *(Midlothian)* (SNP)
Twigg, Derek *(Halton)* (Lab)
† Webb, Suzanne *(Stourbridge)* (Con)
† Western, Matt *(Warwick and Leamington)* (Lab)

Stuart Ramsay, *Committee Clerk*

† attended the Committee

The following also attended, pursuant to Standing Order No. 118(2):

Lewer, Andrew *(Northampton South)* (Con)

Second Delegated Legislation Committee

Monday 28 September 2020

[Mr Philip Hollobone *in the Chair*]

Draft Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020

4.30 pm

The Parliamentary Under-Secretary of State for International Trade (Graham Stuart): I beg to move,

That the Committee has considered the draft Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020.

Mr Hollobone, it is a great pleasure to serve under your chairmanship. I hope the Committee will prove unanimous in its support for the draft regulations and their objective. The regulations perform a laudable function: they will ensure that pharmaceutical companies in Great Britain can continue to produce and sell certain medicines to developing countries at a low cost to help fight key diseases such as HIV and malaria, without the potential drawback of these medicines being reimported into Great Britain for sale at a price lower than the domestic market price.

Many of the poorest developing countries are in urgent need of access to affordable essential medicines for the treatment of communicable diseases and are heavily dependent on imports of medicines, as local manufacturing is limited. Price segmentation between developing and developed countries is necessary to ensure that the poorest developing countries have access to essential pharmaceutical products at heavily reduced prices, while ensuring that fair market prices in wealthier markets incentivise drug development and investment.

Gareth Thomas (Harrow West) (Lab/Co-op): Will the Minister set out for us whether the list of drugs covered by the regulations will be exactly the same as under the current EU regulation?

Graham Stuart: I can so confirm. This is a technical statutory instrument and has no policy content as such.

Pharmaceutical manufacturers will produce large volumes of pharmaceutical products at reduced prices for the developing world only if they are assured that these products will not find a way into developed countries' markets afterwards. The regulations will correct deficiencies in legislation to establish a procedure that identifies the products, countries and diseases covered and prevents the reimport of such products through seizing and disposing, in accordance with national legislation.

Gareth Thomas: One small but potentially significant difference between this SI and the EU regulation it supersedes is that, under the EU regulation, drugs sold only in developing countries have to be marked differently to those sold here. That is not in the current draft of the regulations. Why the change?

Graham Stuart: I am grateful to the hon. Gentleman for his question. I look forward to responding in due course, when suitably refreshed on that important technical point.

The regulations were laid before the House on 2 September and are made under powers in the European Union (Withdrawal) Act 2018. The Committee knows that, given the context, those powers are limited; all that they allow is the correction of technical deficiencies in existing EU law that, by the operation of the Act, were retained in UK law following withdrawal. The draft regulations correct such deficiencies by, for example, replacing references to the European Union, its institutions and legislation with the appropriate UK references. This statutory instrument follows the affirmative procedure because it transfers to the Secretary of State a power that currently sits with the European Commission.

Gareth Thomas: I am grateful to the Minister for his answer to the previous question. The reason it is important is that the markings on the drugs for sale to developing countries potentially make it easier for customs authorities to seize those drugs, recognising that they should not be being sold back into a developed country. However, the draft instrument also does not include the requirement for Ministers—as the previous EU regulation did for the European Commission—to publish a report on the export numbers of drugs. Again, why the change?

Graham Stuart: Obviously, the references to the EU Commission are no longer relevant, and there is therefore no requirement to notify the Commission as under the previous set-up.

Gareth Thomas: My apologies—perhaps I did not make the question clear. It is perfectly reasonable that there is no need to reference the EU Commission, but there is surely a need to report on the number of drugs affected in this way. There is no requirement in the draft instrument, as there is in the EU regulation that it supersedes, for such a report. I simply ask why there is no need, in the Minister's view, for a report on the number of drugs exported under the draft regulations.

Graham Stuart: I thank the hon. Gentleman again. It is worth noting that no drugs have been added to the list under the regulation since 2004. The numbers we are talking about are relatively limited and, as I said, the Commission element is redundant. I am happy to follow up on any need to make sure that the numbers are there and that we remain as transparent in the future as we are today.

The statutory instrument follows the affirmative procedure because it transfers to the Secretary of State a power that currently sits with the European Commission—the power to amend the list of pharmaceutical products covered under the regulations and the criteria for products to remain on that list. The statutory instrument also replaces the requirement that pharmaceutical products, packaging and connected documents should be affixed with an EU logo, with a power for the Secretary of State to make regulations providing for marking, labelling or other identification requirements. I commend the regulations to the Committee.

The Chair: The debate can last until 6 o'clock. I call Gareth Thomas.

4.36 pm

Gareth Thomas: I welcome the chance to respond to the Minister's comments. Access to medicines for developing countries, to tackle HIV and AIDS, tuberculosis and malaria, remains critical not only for the poorest people of the world, but for those comparatively better-off nations, such as ours, as I hope to set out. While there has been huge success over the past 20 years in bringing down the numbers infected with HIV and those dying of AIDS, we need to recognise that there are still just under 1 million deaths a year from them. The regulations therefore remain very important.

Developing countries need to ensure that their citizens have access to the medicines produced by pharmaceutical giants such as GlaxoSmithKline and others. The prices these medicines typically retail at in developed countries would put them out of reach for many in developing countries if prices were not adjusted. Tiered pricing, which is used to make these drugs affordable to the poorest and most vulnerable, was a significant step when it was agreed, and it continues to be an important practice in pharmaceutical markets.

There is legitimate concern that, without the safeguards that the EU regulation helped to create, the unscrupulous would seek to resell essential drugs back to developed countries, such as ours, from developing countries, to create a tidy sum for themselves. The EU's internal assessment of the regulation that this SI supersedes is that it worked extremely successfully, preventing the reimportation into the EU of key AIDS, tuberculosis and malaria medicines. Without the regulations, Britain would suddenly become a very attractive market for the corrupt and immoral wanting to exploit Brexit to export drugs meant for the world's poorest into the UK.

For that reason, Opposition Members will not seek to divide the Committee—tempting as it is, given that we have so many Conservatives sitting on these Benches. However, I have a series of concerns about the drafting of the regulations and their handling by the Department for International Trade, which I hope the Minister will take seriously. If he cannot answer them today, perhaps he will give us a note in writing.

Although the instrument is about trade diversion, I say gently to the Minister that the Department for International Trade does not, from what I hear, have many staff who are specialists in access to medicines in developing countries, or in medicines per se. What is the process for consultation between the Department for International Development, as it was, and the Department of Health and Social Care, which does have expertise in such areas? Perhaps more critically, what process is there for consulting international bodies such as the World Health Organisation?

I do not want the Minister to think that I am disappointed that he is the Minister answering for the Government today, but there is a potential issue with roll-over trade agreements. We are in negotiations with Ghana, Kenya, Cameroon and Côte d'Ivoire to try to roll over trade agreements, but those have not yet been completed. Is there any reason to be concerned that the export of drugs to those four countries, which could reasonably be sold into neighbouring, even poorer countries, might be affected if those crucial trade agreements are not able to be rolled over? I recognise that this is not necessarily the Minister's immediate area of expertise, but it would be good to have a reply to that.

A significant difference in the regulations, as I alluded to in one of my interventions on the Minister, is around the marking of drugs. The current EU regulation requires clear differentiation between the drugs to be sold in developing countries and the same drugs sold in developed countries' markets. A traditional symbol is used to signify medicines: the symbol of Asclepius, from Greek mythology. What is Ministers' aversion to that symbol being used to help demarcate the boundary between drugs for sale in developing countries and those for sale in developed country markets such as ours? It seems an obvious point to help customs authorities and others to seize goods wrongly sold back to the UK and elsewhere. What thought processes have gone on within the Department on that point?

At the moment, pharmaceutical companies themselves or exporters have to apply to the Secretary of State to have a product listed under the EU regulation. What, if any, consultation has there been with developing countries, or experts on access to medicines, to encourage pharmaceutical companies to seek listing under these regulations?

That begs a further question. What are the processes for encouraging pharmaceutical companies to provide drugs for the treatment of other diseases, such as cancers? Rates in developing countries are rising fast. That is not to downplay the significance of AIDS, TB and malaria, but other medical conditions, which have high rates in the UK and elsewhere, are rising fast in developing countries. Similar arrangements may be needed for drugs to treat those conditions, as there are for AIDS, TB and malaria. What action is being taken across Government to encourage pharmaceutical companies to make tiered pricing arrangements available?

Specifically, and topically, on covid, there have been international discussions about making vaccines available to developing countries if they are successfully developed, as we all hope. Presumably they will be quite expensive at first. What arrangements are there for tiered pricing for those products?

The regulations are an important reminder of the huge market failure in getting access to medicines for all those who need them. They are a reminder of the importance of universal health coverage, and the powerful difference that it makes to the health of a nation. We in the UK have a far greater chance of getting the medicines that we need from time to time, because we have a health system with national coverage, and licensing regulation that is usually effective.

The Government's role in the procurement of medicines is critical to helping to lower the price of drugs so that everyone can get access to them. At some point, although I recognise that now is probably not the moment, it would be good to hear what the Government are doing to encourage the newly merged Foreign Office and Department for International Development to continue to work with developing countries to try to get them to extend universal health coverage and stronger regulation of drugs.

The regulations also matter because of the need that I mentioned to get new medicines into developing countries at prices that people can afford. In that context, perhaps

[Gareth Thomas]

it is worth using the example of a successful developed country's handling of covid. New Zealand has been highly successful. It is recognised across the world that its ability to shut itself off from other countries, and the measures that Jacinda Ardern's Government put in place, significantly limited the number of covid cases, in comparison with many other countries, including ours. However, if we want to be an open trading route, it is important to remember what has happened more recently in New Zealand, where visitors to the country brought covid with them, and there have been small spikes in coronavirus infection. That surely underlines the point that we cannot shut ourselves off from developing countries. If diseases develop in them, their citizens may bring those diseases to our country. That underlines the need for systems to be in place to get drugs to everyone in the world who needs them. It would be good to hear what further progress Ministers seek in that regard.

Finally, the regulations remind me of that excellent documentary "Fire in the Blood", from 2013, which tells the story of the international obstruction of access to low-cost antiretroviral drugs that could have been used much earlier in the treatment of HIV and AIDS in Africa. The obstruction was driven by multinational pharmaceutical companies determined to protect their patents and, clearly, their profits. Their obstruction is estimated to have resulted in 10 million to 12 million completely unnecessary deaths from AIDS. The cartel was eventually broken by the Indian generics company Cipla, led by a remarkable man called Yusuf Hamied. The regulations that we are debating are part of the process that led on from that generics company breaking the big pharmaceutical industry's cartel in relation to antiretrovirals going to Africa.

The pharmaceutical industry is now very different, compared with the period covered by the documentary, but the issue of patents and intellectual property remains problematic for the development of, and access to, medicines needed by both developing and developed countries. That subject that deserves further interrogation by the House, but I recognise that now is not the time. As I said, we will support the regulations, but I look to the Minister for answers to the serious issues that we have raised.

4.50 pm

Graham Stuart: I congratulate the hon. Member for Harrow West on his speech, which did two things. First, it thoroughly examined the SI and, secondly, having built that base and confidence with you, Mr Hollobone, it included issues that would adorn any general debate in the House of Commons on health, perhaps straying somewhat beyond the highly technical and specific elements of the regulations. I will respond only to the bits that have some relevance to the SI that we are discussing, notwithstanding the fact that it was an excellent speech and touched on important matters that should, as the hon. Gentleman rightly said, be debated elsewhere.

The hon. Gentleman raised the lack of specialists. We recognise that; he is entirely right. That is why we will work closely with the Medicines and Healthcare Products Regulatory Agency to assess any medicinal information provided by manufacturers or exporters, to ensure that all considerations are given appropriate weight. He will be aware that the Government not only are the first ever—if we are stretching beyond the immediate remit—to meet the 0.7% target for aid spending, but are generously and fully funding the WHO. We will consult as appropriate across the piece.

The hon. Gentleman mentioned roll-over agreements in Africa. I am not aware that there are any practical implications, but if there are any, on further consideration following this debate, I will write to not only the hon. Gentleman but all Committee members so that they are aware of them.

As the hon. Gentleman will be aware, the Secretary of State can make regulations under the SI. On the issue of labelling, the only thing that we are removing is the EU logo. Manufacturers will be able, as now, to work with the appropriate authorities to ensure that their product is suitably differentiated. They have every interest in doing so. Whatever mark they may find best to do so will continue to be supported. As I say, we will have the power to make regulations if further action were to be appropriate, but at the moment we do not think it will be.

Matt Western (Warwick and Leamington) (Lab): How frequently will labelling be reviewed by the Secretary of State, and on what products?

Graham Stuart: I think I can suggest that it will never be reviewed, unless or until someone raises it as an issue, which is most likely to be the companies whose interests we are seeking to protect. We will keep an open mind. We have the power to do these things, and if any problem arises, we will swiftly seek to make changes to ensure that the regime continues to work as successfully as the hon. Member for Harrow West made clear it has to date.

I think "Fire in the Blood", the Government's broader role in procurement, tiered pricing and covid go way beyond this SI, which I hope, as has been made clear, everyone in the Committee is happy to support. I am grateful to all hon. Members for attending today and to the hon. Gentleman for, as I knew he would, giving the regulations a characteristically thorough examination.

Question put and agreed to.

4.53 pm

Committee rose.