PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Fifteenth Delegated Legislation Committee

DRAFT HUMAN MEDICINES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

DRAFT MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

Wednesday 6 March 2019

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Sunday 10 March 2019

The Committee consisted of the following Members:

Chair: MR LAURENCE ROBERTSON

† Ali, Rushanara *(Bethnal Green and Bow)* (Lab)
† Debbonaire, Thangam *(Bristol West)* (Lab)
† Docherty, Leo *(Aldershot)* (Con)
† Doyle-Price, Jackie *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Foster, Kevin *(Torbay)* (Con)
† Green, Chris *(Bolton West)* (Con)
† Jones, Mr Marcus *(Nuneaton)* (Con)
Kinnock, Stephen *(Aberavon)* (Lab)
† Madders, Justin *(Ellesmere Port and Neston)* (Lab)
† Morton, Wendy *(Aldridge-Brownhills)* (Con)
Norris, Alex *(Nottingham North)* (Lab/Co-op)
Reeves, Ellie *(Lewisham West and Penge)* (Lab)
† Robinson, Mary *(Cheadle)* (Con)
Snell, Gareth *(Stoke-on-Trent Central)* (Lab/Co-op)
† Throup, Maggie *(Erewash)* (Con)
† Watling, Giles *(Clacton)* (Con)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)

Jack Dent, *Committee Clerk*

† attended the Committee

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[Mr Laurence Robertson *in the Chair*]

Draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

2.30 pm

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

That the Committee has considered the draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

The Chair: With this it will be convenient to consider the draft Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

Jackie Doyle-Price: It is a great pleasure to serve under your chairmanship, Mr Robertson. In the event of a no-deal Brexit, I am confident that every Member of this House has a shared intention to protect and improve the safety of patients who use medicines and medical devices and, at the same time, enable access to the most innovative of treatments.

Our regulator, the Medicines and Healthcare products Regulatory Agency, otherwise known as the MHRA—not the last acronym that we will rely on this afternoon—has over 30 years' experience as a key regulator in the EU. Its expertise and experience is recognised and respected globally, and we want to ensure that that continues to the benefit of UK patients. It is with that at the forefront of our minds that the UK's plans for the regulation of medicines and medical devices in a no-deal scenario have been developed. Before I set out those plans, it is important to reiterate our real aim of retaining a close-working partnership with the EU to ensure that patients in the UK and the EU continue to have timely access to the safest and most effective medicines and medical devices through the co-operative network that we have built over the years.

As is described in the explanatory memorandums, the system for regulating medicines and medical devices is currently set out in EU legislation. The draft statutory instruments have been introduced to ensure that our national regulatory system continues to function appropriately in the event that the UK leaves the EU without a deal. In developing the regulations, the Department's priorities have been to ensure that the timely availability of safe and effective medicines and devices continues, to minimise disruption to patients and businesses, and to ensure that the UK regulator is able to continue to protect public health.

Members will want to note that the draft regulations have been developed through continued close consultation and co-operation with stakeholders. After a period of informal consultation in August last year, the MHRA published an initial proposal for the UK medicines and medical devices regulation framework, before following that up with a four-week public consultation in October. The feedback of the 170 responses to that consultation led to revised proposals, which were published in January and informed the draft SIs.

I will set out some details of the arrangements and how we have sought to maintain continuity and minimise disruption. First, wherever possible, we have sought to maintain existing arrangements, which should obviously be the first port of call to ensure a smooth transition in the event that we leave the EU without a deal.

With respect to medicines, the UK regulator already operates a national licensing route. In fact, about 90% of medicines used by patients in the UK already have national licences, which will remain valid. The provisions deal with the outstanding 10% of medicines. In the event that the UK leaves the EU without a deal, it will no longer be a part of the European Medicines Agency. The draft regulations therefore provide for the automatic conversion into UK licences of all centrally authorised products and licences, to ensure continuity for patients. One such product is ritonavir, which is a drug for treating patients affected by HIV type-1. The draft legislation deals with specialist products that are not in the national licensing system.

With respect to devices, the UK is already a part of the EU system of conformity assessment for medical devices. That system sets out the standards for pre and post-market assessment of medical devices, and the MHRA is the competent authority within the UK. Those standards will not change, so the draft devices regulations will ensure that UK law aligns with EU regulations in this area after we leave. That is the straightforward part.

In other areas, we have faced a choice regarding the UK's regulatory requirements, and in those instances have sought to maintain current arrangements while ensuring the regulator still has sufficient ability to protect public health. For example, we will continue to recognise batch testing of medicines in the countries we recognise today, which include those in the EU and European economic area. By that, we mean that by becoming a third country we would be seen as importing, rather than as part of the single market. If medicines have been tested by a trusted regulator, we would accept that testing.

We will continue to recognise the CE mark on medical devices and in-vitro diagnostics that have demonstrated their conformity with EU regulatory requirements. It is intended that that recognition will be time limited while we consider the need to revise the UK's system of regulation, linked to the development of new international trading arrangements that the Government are now pursuing. However, any subsequent change would clearly need to be brought before Parliament. For the time being, we plan to maintain the existing arrangements.

There are a few areas in which it has been necessary to add a new requirement as a result of the UK no longer being part of the European regulatory framework. Examples for medicines include a new regulatory hurdle to ensure that medicines do not enter the UK supply chain without having been certified by a qualified person. We are creating a new position within the wholesale licence holder regime, known as a responsible person for import, or RP-I—not to be confused with another RPI. That person will be responsible for providing assurances that such certification is in place, which is a

function of having to maintain a national regulatory system with integrity, given that we can no longer rely on the EMA regime.

We will ensure that all new medical devices and in-vitro diagnostics being placed on the UK market are registered with the MHRA by establishing a new national database for all devices. Obviously, that will be a new cost for business, and the fee will be £100. Manufacturers based outside the UK will be required to have a UK-based responsible person who acts on their behalf to carry out specific tasks, such as registering with the MHRA. There will be a transitional period to enable the industry to implement those requirements.

In conclusion, in the event of a no deal, these draft regulations will put in place a pragmatic solution that ensures the UK's medicines and medical devices regulation legislation continues to function effectively after exit day. The provisions will minimise any impact on patients and businesses and ensure the timely availability of safe, effective medicines on the UK market.

2.38 pm

Justin Madders (Ellesmere Port and Neston) (Lab): It is a pleasure to serve under your chairmanship, Mr Robertson. Here we are again, discussing statutory instruments that would make provision for the regulatory framework after Brexit in the event that we crash out without a deal. That possibility has been known about for nearly two years, since article 50 was triggered, yet this pair of detailed and important draft regulations are being debated only three weeks before the proposed exit date.

The volume and flow of EU exit secondary legislation is deeply troubling in terms of accountability and proper scrutiny. The Government have assured the Opposition that no policy decisions are taken as part of these regulations. However, establishing a regulatory framework inevitably involves matters of judgment and raises questions about resourcing and capacity that I will address in detail later on. It is our view that secondary legislation ought to be used for technical, non-partisan, non-controversial changes, primarily because the legislative accountability process is not suited for anything beyond that. Instead, the Government continue to push through contentious and detailed pieces of legislation with high policy content in this manner.

As legislators, we must get this process right. The regulations could represent real and substantive changes to the statute book. As such, they need proper, in-depth scrutiny. The draft Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 alone are over 200 pages long. The draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 are just under 200 pages long. They cover several EU directives and cannot possibly even be read in the time we have, let alone debated sensibly. We therefore put on record our deepest concerns that the process for these regulations is not as accessible and transparent as it should be.

Decisions made today could have huge implications for a multi-billion pound industry, potentially affecting millions of patients' lives. Yet we are presented with non-amendable instruments with a derisory amount of parliamentary time allotted to debate them. People who voted to restore parliamentary sovereignty might feel that this is a long way from what that should look like. I appreciate that this wholly unsatisfactory approach is not down to the Minister. I thank her for introducing the regulations and for the time that she and her officials gave me yesterday to discuss them, but as the representative of the Government seeking to trample all over proper scrutiny, she has the onerous task of defending this approach, although I believe no one can defend this mess.

As we have heard, the UK participates in an EU-wide system for the testing and approval of medicines and medical devices. The regulations transfer responsibility for those activities to the MHRA—a standalone medicines and devices regulator for the UK—in the event of a no-deal Brexit on 29 March. The instruments intend to ensure the continuity and safety of medicines and devices in the UK, while retaining the UK regulator's ability to take regulatory action to protect public safety. We do not disagree with that objective, which is why we will not oppose the regulations, but that is not to say that we do not have serious concerns about how that objective will be achieved in practice—there are many questions about that.

Although the objectives set out in the instruments are intended to be met with minimum disruption and burden on businesses and the supply of medicines and devices in the UK, we have serious misgivings about how realistic that proposition is.

Thangam Debbonaire (Bristol West) (Lab): My hon. Friend mentions minimal disruption to patients, which the Minister mentioned twice. Does he share my concern that any patient listening to or reading the record of these proceedings, who regularly has to take medicine or receives a medical device, will not know whether the minimum disruption may affect them? That may cause significant distress.

Justin Madders: My hon. Friend is right; we will all have had constituents raise those real concerns. I will go into more detail about what the Government's impact assessment says about some of these issues, which justifies our concerns.

Under the draft regulations, the MHRA, which already carries out a wide range of work, including medicines licencing, pharmacovigilance, inspections of standards and enforcement, will take on an expanded role in the registration, assessment and post-market surveillance of medical devices. Listening to the Minister, we could be mistaken for thinking that that massive expansion in responsibility and bureaucracy will take place with no disruption and with no impact on businesses and patients but, as we have just heard, we have real anxieties about that.

The regulations will enable the UK to continue to recognise prescriptions from the EEA. They provide transitional grandfathering rights for medicines and products that have already been authorised in Europe up to exit date, and provisions that would allow the Secretary of State to make temporary changes to the authorisation process or to allow alternative medicines to be dispensed in the case of potential shortages. Their importance cannot be overstated.

As 29 March is fast approaching, the regulations are increasingly crucial. It is right that we make arrangements, although it is a matter of regret that we are dealing with them in this manner at the last minute. We support

[Justin Madders]

efforts to ensure regulatory continuity, to ensure the ongoing safety of medicines and medical devices entering the UK market and to avoid disruption to the UK supply chain. But we have several questions about the additional cost to businesses, about the MHRA's capacity and resources to take on these additional roles and responsibilities, and the Government's general ill-preparedness to deal with medicine shortages and additional regulations.

Let us start with the impact on businesses. The Government's own impact assessment for the medicines regulations recognises

"a possibility that some medicines that would have been authorised in the UK because of the UK's involvement in the EMA will not be submitted to the MHRA due to business decisions. This could have an impact on access to certain medicines and therefore to public health."

The phrase "business decisions" is, on the face of it, quite innocuous—all businesses make decisions all the time—but the impact assessment almost suggests that such decisions are being made in a bubble, in isolation from the regulatory environment in which they operate.

The impact assessment for the medical devices regulations is a little more explicit. It says:

"It is likely manufacturers would seek to recoup these additional regulatory costs through price increases, which would affect NHS budgeting and spending choices".

That seems at odds with previous assurances. Indeed, the Minister's colleague, the Under-Secretary of State for Health and Social Care, the hon. Member for Winchester (Steve Brine), said in a Westminster Hall debate in November 2017 that one of the three key principles for medicines access post-Brexit was that,

"patients should not be disadvantaged".—[*Official Report,* 21 November 2017; Vol. 631, c. 349WH.]

Yet that is what we are facing now, and it is a damning indictment of the way the Government have mishandled the entire process.

Has the Minister made an assessment of which specific medicines might not now be submitted to the MHRA? Are any particular conditions or patients more at risk than others? What actions has she taken to speak with businesses and ease their concerns about the decisions they will have to make? What public health impacts has her Department been planning for? What contingency plans are in place? Will she clarify exactly which medicines the Department believes will increase in price and by how much, and what the Department will do to avoid the possibility of those costs being passed on to patients or indeed the taxpayer? Has there been a revised estimate of the annual NHS drugs bill, for example, as a result?

The Government's impact assessment also recognises that there will be,

"ongoing costs for businesses currently operating in the UK as they would need to adhere to additional UK only regulatory requirements if they currently sell in the EU/EEA. This includes additional fees, legal and administration costs."

Given that there will also be,

"familiarisation and set up costs as businesses transition into dealing with both systems",

will the Minister confirm whether the Department will be providing any financial relief to the largely small and medium-sized enterprises that will be affected by the changes? What about the MRHA's capacity and funding to take on additional roles and responsibilities? The impact assessment recognises that there will be,

"costs to the MHRA of establishing and sustaining new regulatory capabilities",

although it states that,

"these will be largely recouped through fees."

In light of those statements, I have a number of questions for the Minister. Will she outline whether the MHRA will receive additional funding to support the work it will have to take on independently of the EMA, or will costs be passed on to businesses and therefore, by extension, to patients and the taxpayer? Will she outline more precisely what costs the MHRA will face and over what time period? How much of those costs will be recouped through fees and how soon will those fees be recouped? Will she confirm whether the Department intends to cover any of the additional costs that will not be recouped through those additional fees?

Can the Minister confirm whether the MHRA will be given additional staffing and funding to establish and sustain its new regulatory capabilities? Is she aware of what the make-up of any additional staff would look like and whether that is already in place? If so, how many new staff have already been hired, what training have they undertaken and who is regulating them? Is there, in fact, a ready-made market of suitably qualified and experienced staff just waiting to go and work for the MHRA? That is a critical point in the light of our general debates on NHS and healthcare shortages.

The new framework will be far from the rosy picture that has been painted in some quarters, but before we even consider the effect of what will happen when we get there, there is a basic point for businesses to consider. If they decide to continue to trade in this country, do they know exactly what it is they need to comply with, and by when? One only needs to look at the commencement dates for these regulations to understand the scale of the task ahead of them. The medical devices regulations alone contain over 10 pages of commencement dates, and they are not set out in a user-friendly way at all.

Here is one example, from proposed new regulation 4B of the Medical Devices Regulations 2002. Sub-paragraph (1) says:

"Part VIII only applies before 26th May 2020 in respect of a device or accessory that is a relevant device for the purposes of Part II or III if the conformity assessment that the person placing it on the market or putting it into service relies on for doing so is the conformity assessment required by Part VIII (rather than by Part II or III)."

Sub-paragraph (3) says:

"Where Part VIII applies—

(a) Part II ceases to apply, apart from regulations 7A and 19 (to the extent that those regulations otherwise apply, for which see regulations 4D(1) to (5) and 4E(4)); and

(b) Part III ceases to apply, apart from regulations 21A and 30(3) to (5) (to the extent that those regulations otherwise apply, for which see regulations 4D(6) and 4E(4))."

Another example is proposed new regulation 4E of the 2002 regulations, which states:

"(1) Subject to paragraph (3), regulations 91 to 95 do not apply until the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is

required to publish in the Official Journal of the European Union), unless that date ('the operational date') is before 26th May 2020."

Paragraph (3) states:

"(3) Regulation 91(4) only applies in respect of a device to which Part VIII applies, or in respect of an accessory to such a device—

(a) on and after 26th May 2021 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—

(i) an implantable device, or an accessory to such a device, or

(ii) a Class III device, or an accessory to such a device;

(b) on and after 26th May 2023 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—

(i) a Class IIa device, or an accessory to such a device, or

(ii) a Class IIb device, or an accessory to such a device;

(c) on and after 26th May 2025".

I could go on. [Hon. Members: "More!"] Okay, I will do a bit more, then. *[Interruption.]* Hon. Members are regretting that now. Sub-paragraph (d) states:

"(d) on and after the date which is 2 years after the operational date, in the case of a device considered to be a reusable device, or an accessory to such a device, in circumstances where it is required to bear the UDI carrier on the device or accessory itself."

The proposed new regulation continues:

"(4) If the operational date is before 26th May 2020, regulations 7A and 21A cease to apply on the operational date in respect of a device or accessory to which Part VIII applies because regulation 4B(1) applies.

(5) Subject to paragraph (7), regulations 157 to 160 do not apply until the date which is 6 months after the operational date, unless the operational date is before 26th May 2022."

I am sure that Members do not want to hear any more of that, so I am not going to read out the rest of the regulations, but there are another four commencement dates in proposed new regulation 4E alone, and they are subject to different exceptions and qualifications. At least another dozen regulations contain similar provisions. The Minister will be relieved to hear that I am not going to ask her to explain all those and how they relate to one another. I am conscious that we have limited time, so we would never be able to do that anyway, but how on earth can any business be expected to understand, adjust to and comply with all those different dates without a massively increased burden upon them? What support will be made available to businesses so they can be confident that they are complying with the rules correctly?

I feel the need to lie down after that, but I am going to continue and look at the specifics of the draft human medicines regulations. That statutory instrument relies on the power in section 8 of the European Union (Withdrawal) Act 2018 to amend the Human Medicines Regulations 2012 and modify the effect of the restated EU regulations to ensure that all aspects of retained EU law in relation to human medicines operate effectively and are not deficient after exit day as a result of the UK's withdrawal from the EU.

Will the Minister confirm whether the Secretary of State intends to report back to Parliament on any amendments to existing HMRs after exit day? Will she outline the arrangements for collecting data, monitoring the effectiveness of the regulations and regularly reporting? Will she confirm what bodies will be able to scrutinise performance and delivery, and what assessment has been made of their capacity to take on that additional work?

On pharmacovigilance, in the event of no deal, the sharing of common systems and formal exchange and recognition of data submitted for regulatory activities between the UK and EU countries would cease, and the MHRA would have primary responsibility for the conduct and oversight of all pharmacovigilance activities. The Government's impact assessment recognises that there will be administrative costs to businesses that need to provide that information to the MHRA. Does the Minister intend for the Department to help businesses with those increased costs, and does she have an estimate of what they might be?

On pharmacovigilance information, the draft regulations provide for reporting by the pharmaceutical industry of suspected adverse drug reactions associated with its medicinal products directly to the MHRA database rather than to the current EU database, which is known as the EudraVigilance database. Will the Minister confirm whether, in a no-deal scenario, the UK would be able to access the existing EudraVigilance database, which may be more detailed than the existing MHRA database of pharmacovigilance information?

On serious shortage powers, this contingency legislation enables regulations to be made to modify the application of the Human Medicines Regulations 2012 to deal with serious shortages of medicinal products, which, as we know, is a matter of great public interest. That would replace the regulation-making power in the European Communities Act 1972 for certain limited purposes and would ensure that Government continue to have the power to make temporary changes to the 2012 regulations in a no-deal scenario. That is a clear example of Ministers being given Henry VIII powers over many regulations if they think there is an urgent need because of shortages.

Does the Minister anticipate a doomsday scenario where it will be necessary to use those powers? Or is she saying, "There's nothing to see here; we don't anticipate any problems, but we are going to give ourselves these powers anyway"? Will she outline how the process will be handled if there are shortages and what scrutiny will be available for decisions made under it?

The draft regulations introduce a new targeted assessment route to incentivise novel medicines and biosimilars, which currently use one of the routes involved in the European regulatory network to receive a UK marketing authorisation, or MA, in the same timeframe as today. That involves changes to regulation 58 of the Human Medicines Regulations 2012 and to the Medicines (Products for Human Use) (Fees) Regulations 2016, and may also involve the implementation of further non-legislative changes in order to ensure the

"continued competitiveness of the UK market."

Will the Minister outline what further non-legislative changes the Department intends to implement? Will she outline details of what the new target assessment route will look like in practice? What assessment has the Department made of the impact of introducing the new route, and how does the Minister propose that we will keep in step with, or ahead of, improvements as the EU makes them while we are in the process of exiting and after we exit?

[Justin Madders]

The generics industry expressed concern in response to the Government's consultation about whether the targeted assessment routes would be made available for generics. In response, the MHRA proposed to review that and work with industry to shorten the timings of UK national licensing of generics. Will the Minister clarify the timeframe for the review and outline any progress made towards its completion?

With regard to "legal presence", the medical devices regulations ensure that a UK-based marketing authorisation holder, or MAH, and a UK-based qualified person for pharmacovigilance, or QPPV, will need to be in place for all medicines in the UK. Will the Minister outline how many QPPVs are in operation, what their remit is, what support and training they receive and what net funding they receive? Is the Minister confident that the UK-based QPPVs will immediately have the necessary access to safety data systems for medicines? Can she confirm what ongoing communications there will be between QPPVs based in the EU or EEA and new ones based in the UK? Is she concerned that the additional costs for the UK industry of having to establish domestic pharmacovigilance may make the UK less of a priority market?

Transitional provisions require UK MAHs and QPPVs to be in place within 21 months after exit, to allow time for business to comply. That is especially the case for the QPPV, which is a specialist role. Can the Minister outline the process in that 21-month period? The Government's impact assessment notes that

"there would be a cost to industry in establishing a contact person, MAH and QPPV presence in the UK for those who do not already have a UK presence".

Those costs include a direct cost to change an MAH to a UK MAH and to establish

"premises, familiarisation and administration for the interim contact person or MAH, and QPPV to comply with the new legal requirements, and labour costs for these representatives."

Will the Minister confirm whether the Department intends to help to meet those costs, or will businesses, and ultimately patients and taxpayers, again pick up the tab? What safeguards will be in place, and what are the risks of having our own set of MAHs and QPPVs? Will they require their own insurance? Are there minimum levels of liability that they must be insured for? What is the risk of some random individual being set up as an MAH because there are not people with experience and knowledge available to take up the roles in the first place?

The medical devices regulations ensure that existing centrally authorised products that are currently licensed for the UK market through the EMA will continue to be licensed in the UK in a no-deal scenario. The regulations provide for all existing CAP MAs to automatically be converted into UK MAs, and issued with the UK MA number on exit date, unless the MAH indicates that it does not wish its MA to be converted in that manner. Will the Minister confirm what contingency planning she will undertake if an MAH declines to have its MA converted into a UK MA? Can she guarantee that, in such a scenario, patients will not miss out on medicinal products that are CAPs? Can she outline the cost implications for CAPs of having to supply a full set of data? What will she do if an MAH does not provide that data within one year of exit day?

With regard to packaging, the requirements placed on all actors in the UK supply chain from February this year regarding the safety features aspects in the falsified medicines directive will be removed by the human medicines regulations. Furthermore, this instrument ensures that there will be no obligations on the UK supply chain to affix the safety features or scan packs of medicines. In the interests of public safety, the Government have said that they will evaluate the options for a future UK falsified medicines framework, but ending falsified medicines monitoring without replacing it with a similar UK equivalent is a very serious matter that has clear patient safety implications. Quite simply, it will be harder for the UK to monitor fake medicines coming in from non-EU and EU countries. Will the Minister outline how she intends to resolve that matter as a priority?

The human medicines regulations will also introduce into UK law a new authorised activity as part of the existing wholesale dealer licence, enabling the importation of medicinal products from countries on a list. On exit day, that list will comprise all EU and EEA countries, but the list may change over time. Does the Minister not feel that Parliament should have oversight of those lists, or at least an ability to block or make additions or subtractions, particularly as they will allow medicinal imports?

As we have heard, the medical devices regulations also introduce a new RP-I role to allow wholesale dealers to import medicines from the EU and EEA on to the UK market. Can the Minister confirm how many RP-Is she expects there to be? How will they be trained and regulated? Who will they report to? What arrangements will there be for oversight and holding them to account, including taking legal action against them if there is a concern that they are not carrying out their duties effectively? How will complaints in relation to this new role be handled?

Moving on, the human medicines regulations will allow the recognition of prescriptions from an approved list of countries following EU exit. On exit day, the list will comprise all EEA and EU countries. For a prescription to be eligible, the prescriber must be of equivalent professional status to a profession that is eligible to prescribe in the UK. Will the Minister clarify how oversight will be maintained, to ensure that prescribers are indeed of a professional status equivalent to a profession that is eligible to prescribe in the UK? What will the arrangements be for collecting data and monitoring the effectiveness of these regulations, and how will errors be compensated?

Coming back to medicines, in the event of a no-deal Brexit, there are two possible scenarios for manufacturers marketing biological medicines in the UK. First, where the UK agrees with one or more countries to accept each other's independent test certificates for biological medicines, it would mean little change from the current arrangements, except as agreed and set out in a formal mutual recognition agreement between the countries. What progress has the Minister made in drawing up the list of those countries with which the UK has an agreement in place, and how many countries does she anticipate the UK will have an agreement with by exit day, whenever that is?

Secondly, where there is no mutual recognition agreement in place, that scenario would involve the National Institute for Biological Standards and Control issuing UK certificates for batches of biological medicines used in this country. Where the batch is destined for use in both the UK and another country, if it has already received independent certification in a country that is on the UK's approved country list, the NIBSC will take a public health risk-based approach to deciding whether to rely on a paper assessment of that certificate or to issue a UK certificate to carry out testing.

Will the Minister clarify what is meant by a public health risk-based approach in this context? Can she confirm whether the NIBSC has drawn up a clear set of guidelines by which staff will be making those decisions? If so, is she aware of whether staff have received suitable training in using those guidelines, and will she confirm whether the NIBSC is being given extra resources to manage the extra workload that that will require? Can she guarantee that there will be no time lag in making approvals after exit day?

Looking at the sale of medicines, we see that EU-based online sellers currently have to register, comply with relevant requirements and display an EU common logo linked to the competent authority in which they are based. These regulations remove the requirement for UK-based online sellers. Does the Minister not agree that removing that requirement for UK-based online sellers might make it harder to work out which sellers of medicines online are legitimate?

With regard to manufacturing and wholesale dealing, the current good manufacturing practice directive is preserved, with modifications to reflect the fact that the UK is no longer a member state, but with a regulation-making power for Ministers to modify the directive or replace it in the future. The power is also placed on the licensing authority to publish guidelines on good manufacturing practice and good distribution practice, while preserving the EU guidance in place immediately before exit day until it does so. Can the Minister confirm today that these guidelines will be ready on exit day?

I feel I need to sit down, but I have a few further concerns.

Thangam Debbonaire: My hon. Friend is attacking the detail of these statutory instruments with forensic attention, and I do not envy the Minister in trying to respond to all his many pertinent questions. Does he agree that his analysis of these draft instruments shows that we have been, at best, misled about how straightforward, simple and easy it would be to translate EU regulations, directives and laws into UK law, and also how easy it would be to scrutinise that process? It is important that hon. Members such as him undertake such scrutiny.

Justin Madders: I thank my hon. Friend for that helpful intervention. I feel that we could be a double act on the stage, but I am not sure that we would get many people in to watch us talking about these draft regulations. However, she makes a valid point. We have a lot of these problems because of the foolhardy decision to come out of the European Medicines Agency, which has created an unnecessary amount of work. There are serious questions to answer for those who portrayed leaving the EU as a straightforward matter, and who must now justify our having to interpret, debate and agree this absolute minefield of regulations at very short notice.

I will now talk a little about medical devices. You will be pleased to know that I do not have that much more to say, Mr Robertson; I am sure that the Minister is quite pleased about that as well. I will not go over the section 8 powers of the EU withdrawal Act, but they also apply to the draft medical devices regulations and modify the effects of the re-stated EU regulations, so the questions about reporting to Parliament, oversight and the collection and monitoring of data apply in that context, too.

I also have concerns about the conformity of devices, the expansion of registration requirements and data exchange. The Government announced their intention to continue to recognise, for a time-limited period, the CE mark on medical devices and in-vitro diagnostic devices that have demonstrated their conformity with EU regulatory requirements. Will the Minister clarify what is meant by a "time-limited period", and what the arrangements will be once that period comes to an end? Will she also outline what assessment she has made of the impact of that on access to new devices?

Furthermore, in the event of no deal, UK-based notified bodies responsible for verifying medical devices will no longer be recognised by the EU, meaning that the devices that they have certified will no longer conform to the applicable EU directives after 29 March. What assessment has the Minister made of the impact of not being able to place those products on the market, and what are the Government's contingency plans for that? While UK law will give UK-based notified bodies an ongoing legal status and will continue to recognise the validity of the certificates that they issued prior to 29 March 2019, those bodies will be unable to issue certificates for new products. What assessment has the Minister made of the impact of that on products being developed for the UK market?

With regard to registration requirements, in a no-deal scenario, all medical devices will need to be registered with the MHRA prior to being placed on the UK market. Where a device manufacturer is not established in the UK, the registration of a product with the MHRA will be undertaken by a "UK responsible person", who will be established in the UK with a UK-registered address. That person, as the name suggests, will take responsibility for the product in the UK. Will the Minister confirm how many manufacturers will need to establish a UK responsible person? Will she also clarify the oversight and regulation arrangements for such persons? I note that the impact assessment says that it is uncertain how many people will have the necessary expertise to fulfil that role. Does the Minister have a plan for if enough suitable people do not come forward to be a responsible person?

The draft devices regulations also refer to an appropriate transitional period for people placing medical devices and IVDs on the UK market to comply with the new requirements. The transitional period will vary from between four and 12 months, depending on the risk category of the devices. Will the Minster clarify what the arrangements will be when that transition period comes to an end?

[Justin Madders]

Regulations 76 to 133 of the draft human medicines regulations place a large number of obligations on manufacturers, and corresponding powers to the Secretary of State to require compliance. Who, in reality, will perform that role, and what additional resources will they be given to ensure compliance?

Finally, in a no-deal scenario, the UK will no longer have access to EU data systems, including Eudamed, the European databank on medical devices. These systems are vital for data exchange, facilitating the exchange of information between notified bodies, national competent authorities and the European Commission. The MHRA is building an electronic system that expands on the current registrations database, which the Government say will mirror, as far as possible, the Eudamed requirements. Will the Minister confirm that the new electronic system being built by the MHRA will be operational by exit day? What are the additional costs and where is the funding coming from? Will she outline which aspects of the new database will not mirror Eudamed, and what steps are being taken to mitigate that?

Members will be pleased to hear that I have come to the end of my contribution. I appreciate that I have raised a significant number of questions, and it may not be possible for the Minister to answer them all in the time we have, particularly as we also have to hear from the SNP spokesperson, the hon. Member for Central Ayrshire. The amount of material I have gone through today demonstrates without question why this process is so wholly inadequate for dealing with such important and complicated issues. There are many important questions about the impact on businesses, patients and the taxpayer. We really deserve a better attempt at this than that we have seen today.

3.10 pm

Dr Philippa Whitford (Central Ayrshire) (SNP): It is a pleasure to serve under your chairmanship, Mr Robertson. I thank the hon. Member for Ellesmere Port and Neston and I echo many of his points. I certainly echo his points on the complexity and the short time that we have had to go through the draft regulations. I do not feel that it is sufficient scrutiny for something so technical and complex.

The three main groups affected will be the MHRA itself, the industry—both pharmaceutical and device producers and wholesalers and those who are involved in research and trials—and, thirdly, the NHS and the patients that it serves.

The MHRA will have to massively expand its organisation and its staff. It will have to take on people with skills that it does not currently require. As was mentioned by the shadow Minister, it will also have to develop systems to replace what the EMA has been doing. The EMA typifies one of the benefits that we get from the EU, because we will have to duplicate massive amounts of systems, and we are asking pharmaceutical companies to duplicate staff in the UK and the EU.

The immediate and urgent challenge the MHRA faces is grandfathering the central market authorisations, of which there are about 1,000 from 1995 to 2017. They are central authorisations, and only about a third are held in the UK. It will also have to transfer parallel import licences for similar drugs. The explanatory memorandum cites 21 days. How many of those licences exist? Is it remotely feasible to expect the MHRA to transfer them over within three weeks?

Data access will become more difficult, as this often involves looking at commercially sensitive data. As the UK will not be covered by the European Court of Justice in the future, many companies will be more wary, as they will be asking what their recourse to law will be if they feel that their data has been misused.

In the longer term, the MHRA will have to treble the number of new drug and new agent assessments to produce market authorisations for the UK. It will have to replace the pharmacovigilance work that the EMA does, both the major work and the regular reviews and updates. It will have to replace new data systems, because the UK will no longer have access to EudraVigilance data. That is the key loss—a loss of collaboration.

Although I have tried to raise it, one point that has been overlooked a lot in the past couple of years is the issue of quality control and batch release authorisation. The National Institute for Biological Standards and Control will be leaving the EU shared group of official control authorities on batch release, which means it is losing access to a collaborative network. It will have to ensure that all that work is replaced in the UK. That also means losing mutual recognition.

The MHRA will also have to license people. We heard that there will have to be marketing authority holders and qualified persons for pharmacovigilance for every single company here in the UK, as well as this new creation, the responsible person for import. What will their qualifications be? Exactly how will they be judged and licensed?

I recognise that it is a practical thing just to say that drugs that will be certified in the EU should be recognised in the UK, but this is not driven by our wanting to stay close to Europe; it is driven by the fact that the UK simply does not have enough qualified persons to do it any other way. That shows the threat. This is demanding a big increase in staff and skills, both for pharmaceutical industries and for the MHRA.

Under "Responsible Person", the explanatory memorandum says that a licence holder must

"put in place an assurance system".

Why is it not the Government putting in a single assurance system? Do they really want every drug company to come up with their own assurance system for licences?

MHRA funding has been based on the work that it has done for the European Medicines Agency in the past and on statutory fees. We are told that that will all be replaced through fees: more than £60,000 for a major assessment, more than £50,000 for a major pharmacovigilance assessment and smaller fees for some of the reviews and updates. When we hear so much about a Brexit dividend, why are the Government not looking at putting some funding into the MHRA, particularly in relation to set-up, but also in relation to maintaining these things?

For the pharmaceutical industry, the issue is duplication —having a legal marketing authority holder in the UK and a qualified person. It will mean the time involved in processing the grandfathering of marketing authorities. It will mean the costs of the additional fees, and as I said, those are substantial fees. It will mean a disincentive

to launch medicines in the UK when a fee has to be paid to the EMA and then another fee has to be paid within the UK.

The aim is to negotiate bilateral recognition for batch-testing. How long will that take, and how many jobs are likely to go to the EU? What the paper that I am discussing focuses on is purely drugs being made available in the UK market. Although that is understandable, because it is about the MHRA, there is no talk about what support and help there will be for the industry. Forty-one million packets of drugs go to the EU, and the EU rules are that they need to be batch-tested within the EU. At the moment, 10% of batch-testing is UK only; three quarters is EU only; and only 13% of batch-testing is in both places. There is no talk about what support there will be for the industry. We risk losing those jobs, and the problem is that although those jobs might go first, other jobs tend to follow. Will a big, multinational drugs firm that is opening a new production unit in Europe pick the UK? The chances are that it will not, so the issue is future jobs as well.

Then we come to the NHS and patients. We hear, obviously, about costs for the NHS, because it will have more paperwork to do. There will be delays in accessing new drugs for patients; Australia and Canada have significant delays—sometimes as much as three years. That means that patients will lose access, and there will be an impact on future trials. Trials are always carried out on the best available versus the brand-new. If the UK is not able to deliver the best available drug to patients, it will not be able to take part in future trials.

The papers to which I am referring state that the UK Government will incentivise innovation in relation to rare diseases, but in fact the big step forward in the past 10 or 15 years was collaboration across a population of 500 million people. If we are talking about incredibly rare diseases, the bigger the population from which we recruit people to take part in the trials, the sooner we will find the answer.

As was mentioned, there is also the issue of leaving the falsified medicines directive and the safety packet measures therefore not being required in the UK. Similarly, it is stated that UK producers will not have to register, or to register their products, if they sell online. The worry about devices is that the sheer pressure of all this on the MHRA could lead to shortcuts and to rushing things through to try to keep up.

We have had multiple debates and discussions in the House about the impact of vaginal mesh. That was automatically passed on, because there was no recognition that the device was changing and that the operation to use the device was changing. Unless we have people with expertise looking at these devices, it will be very easy to think that they are exactly the same, but there might be substantial changes in how they work, the materials they are made of and how it is proposed that they will be used. Again, I come back to collaboration. Not sharing pharmacovigilance information through the EudraVigilance database is a real concern to patients in the EU and here.

On shortages, the documentation simply mentions that Ministers will have new powers if there are significant shortages after leaving the EU. I have raised the issue of the Human Medicines (Amendment) Regulations 2019, regarding the serious shortage protocol, which would allow a pharmacist to change a patient's medication without consulting their GP. They do not have access to the patient's medical records, only their prescription. A patient might have been on multiple drugs in the past to reach one that controls their condition. They will not remember all the drugs they were on over the years. They will not necessarily remember which drug caused them to have blackouts or other side effects. Those regulations were put through as a negative SI with no scrutiny and no debate. This measure proposes exactly the same powers.

When I came across the serious shortage protocol, I was shocked to find that there was no consultation with the General Medical Council, even though it would be a significant reversal of medical legal responsibility. I have concerns that in the future such moves on shortages will be simply rushed through, with insufficient cognisance taken of the impact they will have on patients. What other changes does the Minister envisage that Ministers will have powers to enact? Does she not recognise that doing things through the negative procedure does not allow for any scrutiny or debate, and does not allow us to protect our constituents?

3.22 pm

Jackie Doyle-Price: I thank the hon. Members for Ellesmere Port and Neston and for Central Ayrshire for their probing questions. They have both made compelling arguments. I recognise their concerns about scrutiny, but we are where we are. The Government have to make provision for a no-deal scenario, even though we remain determined to leave the EU on 29 March with a deal. None the less, we need to put these statutory instruments in place to deal with the event that that does not happen. Both hon. Members asked probing questions, and I shall try to address all of them. I am sure I will miss some, but I promise to write to them both with full answers to the points they have raised.

Overall, there are concerns about the costs to businesses, patients and taxpayers, all of which need to be addressed. However, I should be up front about this. Clearly, there will be a cost to business. One reason why Margaret Thatcher was such a big believer in the single market was that a single-market regime would reduce costs to business. Therefore, unilaterally leaving the single market will increase costs. We need to be frank and honest about that. We also need to be frank and honest that some of those costs will be passed on to taxpayers and patients. That is a given, but it underlines why we are determined to leave with a deal and minimise any disruption, recognising that we want to make the best out of this scenario for Great Britain.

Some issues were also raised about resources and personnel in respect of the MHRA, which I will come on to. I appreciate that hon. Members feel that they have not had sufficient opportunity to scrutinise this. However, I can assure the Committee that the proposals have been taken forward by MHRA in full consultation with business with a desire to minimise disruption and additional cost, and with a full view to planning to ensure that MHRA is equipped to deal with it. Much of the machinery is in place, given MHRA's role in being such a key player within the EMA.

As I mentioned in my opening remarks, the Government's approach has been to minimise burdens on business while enabling the most robust action for the UK to

[Jackie Doyle-Price]

protect public health. As I have said, I acknowledge that that will place costs on business. The hon. Member for Central Ayrshire explained the disproportionality of EMA costs with regard to what might be replicated with the MHRA. She is absolutely right about that. I can tell her that the fees have been developed based on existing processes. For example, the targeted assessment fee is based on the existing MHRA incoming mutual recognition fee. Furthermore, the MHRA regularly reviews its fee levels and will continue to do so. There is a commitment from the MHRA to review the overall system of fees to the industry following exit with no deal so that we can maintain that they are fair and proportionate to business.

Dr Whitford: Obviously, the MHRA uses a trading fund now and must basically wash its own face financially. Will the Government provide more direct funding to the MHRA or is it envisaged that all of the costs will still be recouped from fees?

Jackie Doyle-Price: On day one of exit under this scenario, the MHRA will, as the hon. Lady says, continue to wash its own face. As to what might materialise subsequently, that would be subject to further discussion. I would not rule out anything at this stage. We are trying to ensure that the business can continue as usual on 30 March if we leave without a deal, but—let us set this in stone—that is if that is the result on 30 March. If we end up in that scenario, we will of course want to make sure that we have got things working effectively. It is also true that we will have to see how relationships work in practice. We can already see that some market practices are preparing for a no deal; others are not. We have said what we are prepared to do to recognise what has happened and what is licensed and goes through the regulatory system in Europe. We are being quite open about accepting that.

The hon. Lady mentioned batch testing, for example. We cannot be sure the same will happen in Europe. We will have to monitor how that works out in practice before setting in stone what the future regulatory regime will be. I come back to my original point: this is for day one of exit to keep the show on the road.

Dr Whitford: The Minister talks about preparing for a no deal, but as the EMA does not have associate membership, most of what is being put in place will be required, deal or no deal.

Jackie Doyle-Price: That is right. As I have said, we are seeing that some parts of industry are preparing for that scenario on the basis that there will be no associate membership. Having left in that scenario, if we look broadly at how the MHRA discharges its functions and how it is funded, at this stage we are looking at it continuing as usual and washing its own face. The hon. Lady mentioned that we could use some of the Brexit dividend to meet the cost. All of that is completely wide open at this stage. This measure is really just to keep the show on the road.

We have put some expectations down in terms of review. Most of the commitments we have made are to review all of the operations within two years. As for any conclusions we reach, we will come back to Parliament to institute any change if that is what we wish to do, but that would be done very much in consultation with industry and in a transparent way, recognising that all Opposition Members are not entirely satisfied. Clearly, we will go back to business as usual when it comes to scrutiny of these matters. Again, I cannot say often enough that I do not want that eventuality to materialise. It is my determination that we leave with a deal.

There was a reference to the impact on SMEs. The MHRA is taking steps to ensure that the burden on them is minimised. It will look at things such as fee waivers for some products to encourage further research and innovation. Again, that recognises the real concern about that.

Justin Madders: I know that we have asked a lot of questions, but there is almost a contradiction in what the Minister has just said. She expects the MHRA to wash its own hands still, but talks about fee waivers in some circumstances. If it is a trading fund, and there are new obligations on it, I am not sure how all that will realistically work.

Jackie Doyle-Price: I trust the MHRA to manage its own finances and take a proportionate view as to what is an appropriate fee, because it has the day-to-day contact with businesses. Overall, it will still be expected to settle its budget on the basis of the fee income that it incurs. That still gives it the freedom to do that, if that is in the sector's strategic interest.

We have responded to some of the representations made by business about the potential additional costs. One reason that we introduced the responsible person for import assurance procedure was to minimise, as effectively as possible, the burden on the trading of the wholesale sector. Again, that recognises that where things have been checked and have gone through an appropriate European regulatory procedure, we should be satisfied that that is good enough for us. I am confident that that pragmatic approach will be repeated as the MHRA takes the matter forward.

Several points were made about the MHRA's ability to take on new roles. The UK already has substantial capacity and expertise to regulate and evaluate the safety of our medicines and medical devices. The MHRA has real expertise in many areas, including pharmacovigilance and clinical trials regulation, which provides benefits to patients across the EU. I am confident that the EU will want to retain access to that expertise. That also shows that the MHRA has the expertise and human resources to discharge those roles. It has 30 years of experience as a lead regulator, it has led on the registration of more than 3,500 medicines, and it is globally recognised for its expertise. None the less, it will manage the demands on its service and I have every confidence in its ability to do so.

The hon. Member for Ellesmere Port and Neston raised the issues of continued access to medicines and of reviewing the fees. The statutory instrument provides continuity for patients and businesses by providing for existing EU licences to be automatically converted into UK licences, which should give continued access to medicines and will be done at no cost to industry. It also puts in place a new licensing route that will allow the MHRA to accept the same information from companies

that apply for an EMA licence and that will allow the UK to grant a licence in the same timeframe as one would be received today.

Effectively, we will follow and replicate what the EMA does. There has been much talk of the UK being rule takers and hon. Members might suggest that there is no change here. That recognises, however, that we are in a global marketplace for medicines and that we all want to have access to the best medicines. In practice, there is much shadowing and sharing of expertise in this area. That raises a question that we do not have time to debate this afternoon, but there is much to be gained from international co-operation in this area.

Obviously, we want to make sure that the UK remains an attractive market for new medicines and for innovation. As I said earlier, we will review the fees set out in the SI within two years to make sure that they remain competitive and fit for purpose, and that they deliver the objectives that we want to achieve through the regulatory system.

The hon. Gentleman laid down a challenge; he said that the regulations go beyond a simple technical implementation of the directives into UK law and raise new powers for the Secretary of State. Clearly, the regulations are made under section 8 of the European Union (Withdrawal) Act 2018, which gives Ministers powers, where appropriate, to take additional powers. However, the changes are the minimum necessary to maintain continuity while protecting the health of UK patients while we are outside the EU, although clearly there is concern about issues of supply, as the hon. Member for Central Ayrshire mentioned.

We do not anticipate needing to use the Henry VIII power. We are confident that the regime that we have set out will ensure continuity of supply. However, in the event that that did not happen, provision would be needed. The power is a safeguard to be used in the case of serious shortages. I would not choose to describe it as a Henry VIII power, but I recognise the right of Opposition Members to do so. It is limited to temporarily modifying the effects of the human medicines regulations, for a limited time or purpose. As has been mentioned, the statutory instrument would use the negative procedure, but it could obviously be annulled. However, it would be used only where existing processes had been exhausted.

The hon. Member for Ellesmere Port and Neston raised the question whether any particular medicines would be at risk, and also mentioned prices in that regard—a concern that I think the hon. Member for Central Ayrshire will share. Clearly the MHRA consulted on the issue, and that informed its analysis. Any potential increase in medicine prices will depend on the extent to which costs are passed on to the consumer; but we shall bear the matter in mind, with regard to future medicines price negotiations. It is something that we shall have to keep an eye on at this stage. It is difficult to quantify. None the less, we have made clear commitments to the public about what they can expect, and about ensuring a continuous supply of medicines, and we shall have to find ways to deliver on those commitments.

Dr Whitford: Is the Minister aware that the Royal College of Radiologists has now produced emergency guidance to nuclear medicine departments, simply because the UK Government did not, on the potential threat of shortage of radionuclides and radiopharmaceuticals, both for scanning and for cancer treatment?

Jackie Doyle-Price: I was not aware of that, but I encourage everyone to participate in the dialogue, because in such an event the whole system would need to be ready. I shall perhaps come back to the hon. Lady on that specific point because, although much of our no-deal preparation is happening within the confines of Whitehall, it is not all being shared publicly.

I emphasise that there have been massive conversations with industry, including those in the life sciences industry—and with charities—about the changes, to make sure that everyone is prepared.

Dr Whitford: The Minister says that preparation is happening in Whitehall that is not being shared with the public, but we are talking about the president of the Royal College of Radiologists. The people who actually deliver scans have not had any guidance from the Government. That is not scaremongering. They have to be ready for something that could happen in a few weeks. They are talking about delaying patients, planning light weeks, and when the molybdenum will arrive, because those things cannot be stockpiled. Why has there not been guidance to the NHS about how to prepare to deal with shortages of radionuclides?

Jackie Doyle-Price: My understanding is that those conversations have been taking place. However, the hon. Lady is right that the very nature of those products, which cannot be stockpiled, has brought complications. I fully expect the president to be involved in those conversations. I do not have that knowledge to hand now, but I will write to her afterwards, to give her some reassurance.

We had two waves of consultations on the draft instruments. For the last, in October, we issued a consultation that received 170 responses, through which we ended up with the proposals before us. Again, these are subject to further consultation with the industry.

It is obviously a priority for us to make sure that Britain remains a competitive location for life sciences companies, and we are committed to maintaining our renowned strength in science and research. Since the referendum, we have seen many signs of the industry's continued confidence in the UK. In 2017, we received the highest level of life science investment in Europe, and were second globally only to the US. That illustrates the confidence in our regulatory system, which is why we are confident that the MHRA is well up to the task given to it by the draft statutory instruments.

The hon. Member for Ellesmere Port and Neston gave an impressive illustration of what he described as the confusion regarding the various dates at which parts of the draft regulations will come into effect and the complexity of some of the references within them, and he posed legitimate questions on how business would understand and prepare for them. However, as I say, we have produced detailed guidance to support everyone in interpreting the draft instruments, and the MHRA does not expect anyone to navigate this alone and will be there to give advice. That support is partly reflected in the length of time that businesses will have to prepare for and implement these measures. We will ensure that that dialogue continues.

The hon. Gentleman also raised questions about market access and legal accountability, and whether we will have sufficient people to discharge that role for the

[Jackie Doyle-Price]

industry. We believe that those skills are already in place, bearing in mind that a lot of companies will already have to fulfil these functions with the EMA, particularly when exporting. We do not anticipate that this change will be disproportionately onerous on business. However, we have given the industry 21 months to implement that aspect. To make sure that only genuinely qualified people undertake that role, anyone who vouches for a medicine that is then potentially harmful to patients faces a maximum two years' imprisonment. The sector has sufficient integrity to engage only properly qualified people; to do otherwise would be foolhardy.

Questions were asked about the degree to which UK consumers could be protected from false medicines. To reassure Committee members, the falsified medicines directive, implemented in 2013, will remain in UK law, even in the event of a no-deal exit. We will make sure that we continue to apply the same protections as before. We obviously want to retain a close working partnership with the EU on medicines regulation, and I think that we will be able to share expertise and information on such issues over and above any potential mutual recognition of regulations. We will all benefit from that information sharing. Issues were also raised about the wholesale sector. We will obviously continue to ensure that the MHRA keeps a good eye on that and makes sure that that regulatory regime is fit for purpose.

Turning to some of the comments about the devices, we will continue to recognise the CE mark on medical devices. It is also fair to say that the existing regulatory regime has perhaps been seen as rather liberal in its approach—the hon. Member for Central Ayrshire alluded to this when she referred to mesh—and it has been subject to some revision at EU level. Certainly, we want to follow what is happening with that review and consider whether there are any further improvements we would wish to make to that CE mark system.

To those colleagues who thought that leaving the EU might lead to a bonfire of regulation, I say that, clearly, when it comes to medical devices, some of which remain within the body for a length of time, we should not stint in our approach to the protection of patients. Patient safety should be the primary objective, notwithstanding the importance of maintaining a competitive marketplace. Patient safety is crucial.

There are estimated to be around 600,000 medical devices available on the EU market, many of which have not been produced in the UK or approved by UK-notified bodies. It would be quite a big undertaking for the MHRA to license those products, but we will increase our market surveillance by requiring all new devices being placed on the UK market to be registered with the MHRA after exit day by the manufacturer or a UK responsible person, in accordance with the transitional timetable. Our emphasis is patient safety first and foremost, while doing our best to improve access to the market. We will require, as the hon. Member for Ellesmere Port and Neston said, all overseas manufacturers to register those products here with the MHRA themselves.

We have also had some discussion about the RP-I. That is a new role; the hon. Gentleman asked how many will be required and where we will find them. We are giving the industry a two-year transition period, to give it the opportunity to register those persons with the MHRA, and it will depend on the number of wholesalers who intend to import products from the EEA. We are satisfied on the basis of the discussions we have had with the industry that that two-year implementation period is appropriate, and there has been consultation on exactly what sorts of skills those persons should have, with the intention that they should fill the regulatory gap caused by our removal from the EMA, but without putting undue burdens on the industry.

Justin Madders: In essence, the Minister is saying that, having consulted the industry, the general view is that there will be sufficient people in place with the right skills within 21 months. If that is the case, that explains the position, but is there a fall-back position if that does not transpire?

Jackie Doyle-Price: As I say, that timescale has been arrived at between the MHRA and the industry. On that basis, I would not anticipate a problem, but we will have to monitor that none the less, bearing in mind that we are effectively introducing a new regime and any market adjustments that happen in that intervening period will have an impact on it. A lot can happen in those 21 months. We are effectively altering the terms of trade, and we cannot be sure of all the consequences of that, but the MHRA will maintain that close dialogue with the industry to ensure that we are being sufficiently responsive.

The hon. Gentleman also mentioned the national database of all devices. The fee for establishing that database will be £100 for each device. Manufacturers outside the UK will be required to have a UK-based responsible person, who would act on behalf of that manufacturer to do things such as registering the product. Again, there will be a transitional period to enable the industry to implement those changes.

Some questions were asked about access to medicines. Obviously, we want to make sure that UK patients have access to life-transforming drugs at the same time as people in Europe. Whether we might be placed at a disadvantage by being outside the EMA has been a real concern. We want to ensure that when a drug is registered with the EMA, we consider it at the same time, so that there is no advantage for any manufacturer in delaying entering the UK market because it would not get any ongoing benefit from that, in terms of protective rights on intellectual property. We would effectively start the clock at the same time as the application with the EMA to give an incentive to enter the UK market as soon as possible. Again, we will wish to monitor how that works in practice.

We will assess whether countries from which a registered importer operates might change over time, and whether that needs scrutiny by Parliament, on the basis of whether the technical standards in that country are consistent with ours. Obviously, that would be a constantly moving feast. The MHRA is ideally qualified to make a judgment on that, but I would expect it to do that with sufficient transparency to allow any challenge to take place.

I apologise if I have not addressed all the points that have been made this afternoon. I will write to hon. Members. I reassure all hon. Members that the Government are fully committed to a system of medicines and medical

device regulation that intelligently balances patient access to new, innovative and world-leading projects. As part of these measures, the MHRA will have in place a suite of licensing routes for medicines and vigilance systems for medicines and devices. The Government also place enormous value on the contribution to public health of the research charities, industry and the life sciences sector as a whole, and as such, the MHRA will continue to support innovation in the life sciences through its innovation office and scientific advice.

We remain committed to offering a competitive regulatory environment to ensure that the UK has access to the safest and most effective medicines in the world. As I said, we have tried to replicate the current regime, but there has been a need to add additional requirements for industry to deal with the fact that we are leaving the EMA and its regulatory structure. We have done so in the most competitive way possible, while maintaining patient safety and remaining the best place in the world for science and innovation.

Question put and agreed to

Resolved,

That the Committee has considered the draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

DRAFT MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

Resolved,

That the Committee has considered the draft Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.—*(Jackie Doyle-Price.)*

3.54 pm

Committee rose.