PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT
GENERAL COMMITTEES

Public Bill Committee

MEDICINES AND MEDICAL DEVICES BILL

First Sitting

Monday 8 June 2020

(Morning)

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not later than

Friday 12 June 2020

The Committee consisted of the following Members:

Chairs: Ms Karen Buck, †Philip Davies

† Ali, Rushanara *(Bethnal Green and Bow)* (Lab)
† Browne, Anthony *(South Cambridgeshire)* (Con)
† Churchill, Jo *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Davies, Gareth *(Grantham and Stamford)* (Con)
Day, Martyn *(Linlithgow and East Falkirk)* (SNP)
† Double, Steve *(St Austell and Newquay)* (Con)
† Everitt, Ben *(Milton Keynes North)* (Con)
† Fletcher, Katherine *(South Ribble)* (Con)
Hudson, Dr Neil *(Penrith and The Border)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† O'Brien, Neil *(Harborough)* (Con)
† Rimmer, Ms Marie *(St Helens South and Whiston)* (Lab)
† Robinson, Mary *(Cheadle)* (Con)
† Throup, Maggie *(Lord Commissioner of Her Majesty's Treasury)*
† Western, Matt *(Warwick and Leamington)* (Lab)
Whitford, Dr Philippa *(Central Ayrshire)* (SNP)
† Whittome, Nadia *(Nottingham East)* (Lab)

Rob Page, Yohanna Sallberg, *Committee Clerks*

† attended the Committee

Public Bill Committee

Monday 8 June 2020

(Morning)

[Philip Davies *in the Chair*]

Medicines and Medical Devices Bill

11.30 am

The Chair: Before we begin, I have a few preliminary points to make. Members will understand the need to respect social distancing guidance, and I will intervene if necessary to remind everyone. I also remind Members to switch electronic devices to silent, and that tea and coffee are not allowed during sittings.

Today, we will first consider the programme motion on the amendment paper. We will then consider a motion to enable the reporting of written evidence for publication, and I hope we can take these matters without too much debate. The *Hansard* reporters would be most grateful if Members emailed any electronic copies of their speaking notes to hansardnotes@parliament.uk. I call the Minister to move the programme motion, which was agreed by the Programming Sub-Committee last week.

Ordered,

That—

(1) the Committee shall (in addition to its first meeting at 11.30 am on Monday 8 June) meet—

(a) at 3.30 pm on Monday 8 June;

(b) at 9.25 am and 2.00 pm on Wednesday 10 June;

(2) the proceedings shall be taken in the order shown in the first column of the following Table;

(3) the proceedings shall (so far as not previously concluded) be brought to a conclusion at the times specified in the second column of the Table.

TABLE

Proceedings	*Time for conclusion of proceedings*
Clauses 1 to 4	1 pm on Monday 8 June
Clauses 5 to 11	6 pm on Monday 8 June
Clauses 12 to 26; Schedule 1; Clauses 27 to 33	11.25 am on Wednesday 10 June
Clauses 34 to 36; Schedule 2; Clauses 37 to 45; new Clauses; new Schedules; remaining proceedings on the Bill	5 pm on Wednesday 10 June

—(Jo Churchill.)

Resolved,

That, subject to the discretion of the Chair, any written evidence received by the Committee shall be reported to the House for publication.*—(Jo Churchill.)*

The Chair: Copies of written evidence that the Committee receives will be made available in the Committee Room.

We now begin line-by-line consideration of the Bill. The selection list for today's sitting, which shows how the selected amendments have been grouped together for debate, is available in the room. Amendments grouped together are generally on the same, or a similar, issue. Please note that decisions on amendments do not take place in the order they are debated, but in the order they appear on the amendment paper. The selection and grouping list shows the order of debates; decisions on each amendment are taken when we come to the clause that the amendment affects. We will begin with amendment 9 to clause 1.

Clause 1

Power to make regulations about human medicines

Alex Norris (Nottingham North) (Lab/Co-op): I beg to move amendment 9, in clause 1, page 1, line 5, at end insert

"for a period of two years following Royal Assent."

This amendment provides a sunset provision for the Bill requiring the Government to return with primary legislation.

It is a pleasure to serve under your chairship, Mr Davies. As the shadow Secretary of State for Health and Social Care said on Second Reading, we understand the need for, and urgency of, the Bill. We will therefore be supportive during its passage, but we will seek to improve it. These improvements will take three forms: a focus on patient safety, a focus on promoting greater transparency about the development and use of medicines and medical devices, and seeking to contain the massive and extraordinary powers the Secretary of State is securing for himself.

I am conscious, certainly in this first sitting, that we have an awful lot on. I hope that colleagues will be understanding if it feels like I am moving at pace, because there is quite a lot of ground to cover. However, I wanted to say how grateful I am to the Clerks for having helped me put these amendments together, and to the Minister and her officials for their constructive support so far. The tone of discussions about the Bill has been really good, and I am sure we will continue in this way.

Finally, a lot has happened since the First Reading of the Bill, not least the fact that I have taken over from my hon. Friend, the unstoppable Member for Washington and Sunderland West (Mrs Hodgson), as the Opposition public health lead. As I have been telling stakeholders, they will probably find me similar in approach—committed, but in good humour—but perhaps lacking the same colourful jackets.

This is an enabling Bill. It is a necessary Bill, but we cannot give the Government a blank cheque. We are talking about the power to decide critical, life-and-death matters involving medicines, devices, humans and animals, and we should not just wave that off to secondary legislation without understanding what that might mean and whether there might be a better way to do it. As such, amendment 9 seeks to put a limit on that power.

The proposed arrangements allow the Secretary of State and his successors to make hundreds or more individual decisions to change our current regulatory regime into a markedly different one, one statutory instrument at a time, which I do not think is desirable. Instead, this amendment offers the Secretary of State two years of that considerable power, but asks him to return in two years' time with a comprehensive set of regulations across medicines for both humans and animals;

for medical devices; and, critically, for the proposed new regime surrounding the Medicines and Healthcare Products Regulatory Agency.

That would provide a chance for proper consultation across the sector, including with patient groups, industry bodies and interested companies, as well as more parliamentary scrutiny to set up the regime that we all want—a safe one, an effective one and a world-class one. It would also give us two years of life outside the European Union and would really help us to land in that place and find out how different we intend to be, certainly in this sector. It would provide time for piecemeal change, but it would at least then reset things, and then I would be at the point where I would be much more relaxed about the use of secondary legislation to diverge from that as circumstances require, because we would have reset things in the full knowledge of Britain's new place in the world.

There is a case to be made that the arrangements being proposed in the Bill reflect current arrangements; after all, we do not have parliamentary scrutiny over the regulations that have come traditionally in previous decades from the EU. However, that is a political argument—a very effective one—and we know that, outside the white-hot light of public debate around the EU, the EU works differently from that. That was a theme developed by the Member for Central Ayrshire on Second Reading.

Page 4 of the Government's impact assessment of the Bill describes how a higher-risk medical device enters circulation in the UK for use, saying that for a high-risk medical device to enter the market "a Notified Body"—for us, that is the Medicines and Healthcare Products Regulatory Agency—has to "certify" it. So far, so similar—that is essentially what the Bill would allow, as well. However, at the moment the device would be checked by two further notified bodies from within EU structures and the European Commission, as it says on page 5. That is quite a protection; that is a triple lock. It is not just our own MHRA saying whether or not a device is safe; there are two other equivalent bodies saying that, too.

That system will go and instead we will have a Secretary of State, we will have a Department, and I am sure that NHS England will have a view, too, but fundamentally we will just have a Committee of the House—a statutory instrument Committee. That is quite a diminution. Surely we at least need to know that there will be adequate safeguards in place. If the Government do not accept the amendment, I would be very keen to know what can be done to protect that triple lock.

I will move on to tell a story about two page 10s. Paragraph 42 on page 10 of the impact assessment refers to the potential to move to "hub and spoke dispensing" for pharmacy. That is a very live debate in the field of pharmacy at the moment, I have to say. I have probably not checked this with the shadow Secretary of State, but I see some positive arguments for it, although I can also see significant risks. It is the sort of thing that I think parliamentarians from all parties will be very interested in. I think that we would form different views on it, and not on party lines, because we are basically saying that pharmacy changes—that it is less about dispensing and more clinical, and that bigger nationally based pharmacies, as it were, will instead provide an outsourced dispensing arm. I can see efficiencies in that system; we are doing an awful lot of that at the moment in the context of coronavirus. However, that would be a radical change for pharmacy. At the moment, paragraph 42 on page 10 of the impact assessment says it is a potential direction for where things will go for pharmacy.

If we look at the Bill, we do not see the words "hub and spoke" anywhere, which is very significant. I gently say to Back-Bench Members of the governing party: "You could be in a situation in a year's time where you are in a statutory instrument Committee being asked, basically, to make the most significant change to pharmacy in decades, and one that you will get a lot of emails about from your local pharmacists, certainly in community pharmacy, and I really do not think that is the sort of power that the Bill is intended to give."

I said that this was a story of two page 10s. Page 10 of the delegated powers memorandum refers to clause 1 of the Bill and justifies the use of delegated powers:

> "The human medicines regulatory regime is ever-changing and requires technical changes in order to keep up to date. These are changes we cannot predict in advance and therefore would not be practical or appropriate for these amendments to be made through primary legislation each time an update is required."

That is saying, "Something changes a little bit and we would not want a whole new law to keep pace." Of course, I understand that. However, we are talking about something really significant here; I would argue that it is an entire model change for pharmacy. We know that this is of interest to the Government, because it is in their own impact assessment. They say that it is a possibility. We really need to square that.

I accept that the Secretary of State will need powers and will have to do things through secondary legislation to keep us up to pace with, or to diverge from, European regulations. However, I am not confident that this is a mandate to make really significant changes to something that is very important to us all. That is why I have moved amendment 9. It would say to the Secretary of State, "Go and have a look at this for a year-plus, and then develop legislation to reset that." Let us have proper consultation with the sector and with citizens. Let us have proper parliamentary scrutiny. Then, if we come to the view that this is the best way to do it, by all means that is what we should do.

I hope that the Government are minded to accept the amendment, but I am sceptical of that chance, so I would be keen for the Minister to return to these two points. First, will this provision mean a diminution of protection, certainly when it comes to the triple lock on medical devices? Secondly, there needs to be at least an acceptance from Government that the liberty to make quite big and bold changes is not licence to make any changes that they want, bolstered by a Committee majority, because I do not think that that is in the spirit of the legislation or of this exercise, which is about getting us to a safe position following the end of the transition period.

The Parliamentary Under-Secretary of State for Health and Social Care (Jo Churchill): It is a pleasure to serve under you, Mr Davies. I agree with the hon. Member for Nottingham North that we have worked on the Bill in a spirit of co-operation, and I would very much like that to continue, because sitting at its heart is the patient, and patient safety is what we are after here. I

[Jo Churchill]

will come on to the two specific points, but I shall address now the sunset element and why, in our opinion, that is not the way to proceed, because of its time-limited nature.

As the hon. Gentleman said, the Bill is necessary because at the end of the transition period, we will lose the ability to update. I am grateful for his words saying that both he and the shadow Secretary of State for Health and Social Care understand what we are trying to do. We need to be able to amend the legislation that governs human medicines and medical devices and veterinary meds. This measure will enable us to update the regulations in the light of patient needs and in the light of changes and innovation. I am sure that the hon. Member for Nottingham North would agree that one challenge is the dynamic nature of how medical devices in particular, but also medicines, are changing—at the bedside, but also right across healthcare. Patients and their best interests are at the heart of the Bill, and that is where I want to start.

On amendment 9, what the hon. Gentleman says is important, but the explanatory statement, while giving clarity, still leaves us with the challenge of an overarching sunset clause for the Bill, such that two years after Royal Assent, the primary legislative framework would fall away and Parliament would have to re-legislate for the provisions in the Bill once again. I understand that the hon. Gentleman's intention is to ensure that Parliament reconsiders, and those checks and balances are important —it is important that we think about the legislation that we are passing. One would hope that at that time, Parliament will be sitting under normal circumstances, but, to be frank, we are not sure. That said, I would like to set out specifically why this proposal would be unhelpful and cause a potential risk to patient safety.

The Bill, in the main, does not deliver any immediate change to the regulation of medicines and medical devices. It provides a framework of powers to ensure that regulatory change can be made as and when necessary. It does, as I hope all hon. Members will recognise when we reach the relevant clauses, increase the level of parliamentary scrutiny, and it is that that enables us to look before something goes forward. There is going to be more scrutiny, under the affirmative procedure, for us to look and understand what it is we are legislating for than we have had thus far. Use of the affirmative resolution is made near universal, other than in the event of an emergency and for very minor changes.

11.45 am

The Bill delivers clarification of the enforcement powers available to the MHRA in respect of medical devices by consolidating offences. It introduces civil sanctions as an alternative to prosecutions, and concentrates the MHRA's various tools to ensure compliance with the medical devices regulations in one place. Such strengthening, and introducing a necessary power of disclosure of information, rights a wrong that has been in place for some time: the inability to share information throughout the NHS family if there is a concern about a medical device. I know we all welcome that. It is, arguably, an additional lock to what we currently have, because the data is shared.

If the Bill were to be sunsetted two years after Royal Assent, I cannot see what benefit that would bring because it would still be appropriate in relation to the powers in clauses 1, 8 and 12 to make changes to the regulatory regime through secondary legislation, which would necessarily require primary legislation to do it—that, again, would give assurance. To have the Act fall away after two years would run the serious risk that we would cease to have the legal powers we need available to us to make regulatory change to address a patient safety risk or to improve access to medicines and all innovative therapies that might be coming onstream at that point.

As we know, the passage of the Bill has taken some time and a hiatus would be extremely detrimental to patients. Also, we might not be able to deliver reforms such as the ones alluded to by the hon. Member for Nottingham North on community pharmacy. As he knows, we are already six months into the Bill and we are just beginning our consideration. It is entirely conceivable that in two years' time, we might not be able to secure the necessary powers on the statute book in order to use them. I ask for his forbearance in not pushing this matter, because a sunset clause could lead to further unintended consequences. I therefore do not think it is necessary.

We will need to make changes to human medicines, veterinary medicines, clinical trials and medical device regulations. The changes range in nature from the very minor but important, such as the ability to have Braille printed on medicine packages, to updates to the marketing authorisation process. For example, innovative therapies have tailored manufacturing requirements that reflect the deterioration of specific short-life components, and we would want to do that if we knew that the lifespan of the component was compromised. The changes can be extremely specialised, and secondary legislation is the appropriate vehicle for such changes. Where the changes are critical to patient safety, it is absolutely right that we can make them quickly and not worry about the powers to do so falling away, which would leave us hobbled in our ability to care for the patient.

I understand the concern of the hon. Member for Nottingham North about delegated powers and their breadth, given the points raised in respect of other Bills. However, our substantial delegated powers memorandum sets out the limits and curbs on the powers available, and the safeguards applied to them. To further assist, we have published a draft of six illustrative statutory instruments as examples of how the delegated powers in the Bill may be used. That is in accordance with the recommendations in the Delegated Powers and Regulatory Reform Committee's recent report. I very much want to reassure him about that.

It is necessary to regulate such matters through secondary legislation, as they are technical areas comprising a large body of law built over time that reflect a highly complex area where small changes may make a difference to good regulation. That is why it is important to have that flex. Small changes to the human medicines regulations might have a significant bearing on one element of the regulatory regime, but have no impact whatever on how medicines are supplied and so on. It would be unwieldy at best and dangerous at worst to rely on primary legislation for any change to the regulation of medicines, medical devices and clinical trials, given the necessity for speed when changes are needed. We might put

ourselves in the position of continually needing to return to Parliament, potentially with emergency legislation every so often, to put something right that provides a material benefit but is of little consequence, which could be done via a statutory instrument, and putting off updating regulations until enough change is required that a Bill becomes paramount. Meanwhile, where changes were not made, there would be those who would obviously be affected because we would have failed to take action when it was needed for those individual patients.

I am sure that the hon. Member for Nottingham North would not want the UK's regulatory regime to stagnate. I know that he supports a vibrant life sciences sector, as I do—particularly given the part of the country he represents, with its great university—where we can encourage innovation and access to innovative therapies, tempered with the need to protect our patients. Without the ability to update and amend regulations by secondary legislation, we run that risk.

The substantive powers in the Bill are necessary. There could be unintended consequences if the Act falls away and we have a gap, such as whether the MHRA would continue to have in its arsenal the necessary equipment to deal with serious harms, or whether there could be challenges in securing compliance.

The power to disclose within the NHS family is new. A combination of EU legislation, and the way it has been implemented in the UK, has prevented us from being able to, for example, tell one NHS trust that alerted the regulator to an issue that other trusts had raised similar points, so we do not build the picture of patient safety across trusts. I know that the hon. Member for Nottingham North has approached the Bill with patient safety in mind, as I have, because we have discussed it, and I have had conversations with the hon. Member for Central Ayrshire over the weekend, as has the hon. Gentleman.

We are all trying to get the Bill to a place where the patient is at the centre and their safety comes first. I hope that the hon. Gentleman and other hon. Members appreciate the significant benefits and coherence that the power would bring for patient protection. It ensures that information for patient safety travels through the system, and it provides another lock on the system to ensure that information is received rapidly for the protection of patients.

To that end, sunsetting the Bill would present more harms than it would address, but that would not be the true impact, however well intentioned. The impact would be by virtue of where the amendment falls in clause 1(1), on the ability to update and amend the law in relation to human medicines. The same arguments relating to why that would be unhelpful apply, but it is also unclear what the intent would be with respect to regulations already made under that clause. We would not wish inadvertently to undo change to the statute book, for good reasons and in the interests of Parliament, so that Parliament can return to the principles of the Bill on each occasion, rather than the specific changes necessary to improve the regulation of human medicine.

I understand that the aim is to ensure that Parliament can consider the matters thoroughly and that the amendment is about scrutiny. I hope that in our consideration we can address any material issues now, so that Parliament will not need to do so again.

On the hon. Gentleman's concerns about pharmacy, which I will come to later, essentially it is about ensuring that community pharmacies are enabled. I am cognisant that we wish to empower small pharmacies to be able to use a hub and spoke model to secure their place on the high street and to ensure that, with appropriate training for technicians, the clinician can be freed to move forward, as per the pharmacy contract, to give advice to patients as part of the primary care team. That is what, in essence, lies behind the desire for pharmacy to be enabled, in order to deliver more for patients and for pharmacists, who are highly skilled and to whom I pay tribute. They have been a stalwart part of the entire system through the past 12 weeks. They have met patients in the high street and their doors have remained open. This legislation will enable them to be the fine clinicians that we know they are, and to use their high level of skill to benefit others.

Alex Norris: I take the point about not wanting to rely on primary legislation all the time. I would be much more comfortable—in this Bill in its entirety, but certainly in any future legislation—with provisions for technical updates. Nobody would think that we would need to return to primary legislation, especially not in an emergency, but I do not think that anything in the clause says that would have to be the case. I would probably accept that two years is too short a period, given the amount of work that has to be done prior to something coming into law. However, that might be an argument for a greater sunset clause rather than none at all.

I did not quite agree that nearly everything would be covered under the affirmative procedure. I am very happy to be wrong on this, but the delegated powers memorandum states, on clause 1 alone, that the scrutiny will be by the affirmative procedure

"with the exception of…the labelling and packaging of human medicines…advertising human medicines…prohibitions in the supply provisions for human medicines…the charging of fees in relation to human medicines"

and emergency powers.

If we discount the emergency powers because of the need to move quickly, we are still talking about the labelling, advertising, prohibiting and charging of fees for human medicines. Those are quite significant areas that will not be covered under the affirmative procedure. That may be a distinction without a difference, given that fundamentally there are devices that the Opposition could use if we wanted those to get an airing. However, it is important that hon. Members know that not everything will be covered by the affirmative procedure except for some very small elements.

Finally, I really appreciate the clarity on the hub and spoke model, for which the Minister made a very strong case. The argument is going on sector-wide. I do not think that there has been much of a political conversation on it. I cannot remember it in the Conservative manifesto, but I might be wrong. It feels a little bit as though we have reached the conclusion without having done all the work behind it—the Minister may well have done; I mean more generally.

Jo Churchill: This will be done in consultation with pharmacists, in a discursive way. As the hon. Gentleman has articulated, we have found ourselves in unusual times. Ensuring that we seize the advantage, in a way that is clear, transparent and consultative, is the aim of what we are trying to set out.

Alex Norris: I am grateful for that clarity, which gives me much reassurance. All I will add is a request that the Government include Opposition parties in that. For something this sensitive, forming a political consensus would be good for everybody. I do not intend to press the amendment to a Division, although we are likely to return to it at future stages. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Alex Norris: I beg to move amendment 22, in clause 1, page 1, leave out lines 10 to 16.

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

The Chair: With this it will be convenient to discuss the following:

Amendment 23, in clause 1, page 2, line 3, at end insert—

"(5) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of human medicines."

This amendment requires the appropriate authority to consider patient safety first when making regulations under subsection (1).

Clause stand part.

Amendment 24, in clause 8, page 5, leave out lines 18 to 24.

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

Amendment 25, in clause 8, page 5, line 32, at end insert—

"(5) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of veterinary medicines in relation to animals, humans and the environment."

This amendment requires the appropriate authority to consider animal, human and environmental safety first when making regulations under subsection (1).

Amendment 26, in clause 12, page 7, leave out lines 26 and 27.

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

Amendment 27, in clause 12, page 7, line 27, at end insert—

"(3) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of medical devices."

This amendment requires the appropriate authority to consider safety first when making regulations under subsection (1).

New clause 3—*Report on availability of medicines*—

"The Secretary of State must report to Parliament when a medicine which is clinically beneficial has not been made available on the NHS."

This new clause requires the Secretary of State to report to Parliament when a medicine which is effective has not been made available on the NHS.

Alex Norris: Turning to clause 1, page 1, subsection 2, as we might have said at school—I think this is verbal reasoning, if my memory is good enough—one of these is not like the other. As the Minister said, and as I think every person in the room and indeed across the House would say, the most important thing is patient safety. The human medicines regime must be safe. There is no doubt about that, and I know that is a personal priority for the Minister and something that she works very hard on.

Similarly, availability is crucial. We all want everybody in this country to have access to the vital medicines and medical devices that can enable them to live full, happy lives. We know that is challenging. Since I am here, I might cover new clause 3, which is essentially the Orkambi clause. Hon. Members who were here in the previous Parliament will know what a difficult and perhaps even unedifying process it was to get a much-needed medicine on to the market to give relief to thousands of people in the UK, and how frustrating and ineffective it was—for whatever reasons people would think that was frustrating—over a number of years to get from the place of this thing existing and being available to some people in other parts of the world but not in the UK. What could be more frustrating?

12 noon

For the aid of parliamentary scrutiny but also, dare I say it, for the ability to build support across this place for ensuring that people have access to the right drugs, new clause 3 merely asks the Government to publish the list of what sort of human medicines they think are out there that we cannot seem to get access to. That would be a useful jump-off not only for scrutiny, but hopefully for support, because we know that we want these things to be available to people in this country.

The third one is attractiveness. We have had safety, availability and now the attractiveness of the UK to research and manufacture. I get this; both the Minister and I attended the University of Nottingham, so we know that this is one of the great things that Nottingham is doing really well. It is one of the great success stories of the past 15 years. We used to go down a pit and make cigarettes, and now we are inventing ibuprofen and the magnetic resonance imaging machine.

We have an awful lot more to do there, but the life sciences sector is critical. It is an anchor sector for the UK economy, but for us in Nottingham and our regeneration it is crucial: not only good jobs today, but good jobs that will be here tomorrow, too—nearly 40,000 of them at the moment, contributing nearly £10 billion to the UK economy each year. Any Government would have a significant interest in protecting and developing that, as indeed would any Opposition, so I understand the position, but is it on the same statutory footing as safety and the availability of medicines? Attractiveness, like beauty, is in the eye of the beholder rather than the beheld. We are talking about massive multinational corporations, almost little countries in their own right, which we know to be litigious and exceptionally aggressive in their lobbying.

I will be willing to take the Minister's reassurance on this, given that I know she will take significant legal advice on this, but does having this on the face of the Bill not create a set of circumstances where there will be lobbying or even legal pressure regarding attractiveness being on the same footing as patient safety? A Secretary of State's decision might as a result be challenged for not giving the same regard to attractiveness as it did to safety. I do not think anybody would want that, so I hope the Minister will be able to outline her latest guidance on that, and perhaps on top of that either

what the definition of attractiveness will be, or when we might know. I suspect that will possibly be in the regulations, but I am keen to know that, since it came up on Second Reading.

Turning to amendment 23, if amendment 22, which would take attractiveness out altogether, is not the way to do it, then perhaps we might do a little better to create a clear hierarchy. I do not think this would be a particularly revolutionary concept, as my hon. Friend the Member for Leicester South (Jonathan Ashworth) said on Second Reading. Let us establish a hierarchy and say that we think patient safety is the most important of those three things—we want all three, but that is the most important.

Not only for hon. Members who were here in the previous Parliament, but for those here to this day, Primodos, sodium valproate and surgical mesh spring to mind. It is important at this point to pay tribute to campaigners such as Impact and the Association for Children Damaged by Hormone Pregnancy Tests, and I am grateful for their support in developing my remarks. We have the potential for a really big moment on patient safety, certainly on those issues.

Rushanara Ali (Bethnal Green and Bow) (Lab): It is absolutely right that there should be some way of setting out a hierarchy, with public safety at the top. Like my hon. Friend, I have a major project in my constituency to promote the life sciences, through The Royal London Hospital, Queen Mary University of London and others. It would be great for investment and we want to see that happen. However, in the light of what has recently happened and the public loss of confidence in the focus on public safety, particularly with reference to chlorinated chicken and the rest of it, the public feel great concern about safety. It is important that the Minister is able at least to provide the reassurance that public safety would be at the top of the agenda, with some sort of hierarchy.

Alex Norris: I completely agree. I think that if we stood in the street for a bit and just straw-polled people, everybody would say that safety is uppermost and they would see the value in its being set on a higher tier, which is what I am suggesting. We are at this possibly significant moment—I believe it is 8 July—when the noble Baroness Cumberlege will come back with her review into what has happened. Obviously, it is a sign of the times and where we are, but at Second Reading people talked about it coming out in March. The world has passed us by, but I understand that publication of the review is imminent and I am keen for that date of 8 July to be confirmed.

If the review says that there are issues around patient safety, we would expect there to be recommendations and changes, which I think is reasonable. I will return to this theme later in the day. What might this say about the MHRA? Is it possible that the regime that we seek to put in place through the Bill might be overrun by events? If recommendations come out of that, is there a possibility of revisiting that in future stages to be clear about it? That is an argument against the sort of piecemeal regime that the Bill proposes, instead of coming back in, if not two years, then three or four, to set a full codified bringing together of the different Acts into one Bill.

I will finish on amendment 23 by referring to one of my favourite contributions from Second Reading:

"Patient safety is not a partisan issue; it is paramount."—[*Official Report,* 2 March 2020; Vol. 672, c.689.]

The Minister may recognise her words. I completely agree with her.

Amendments 24 to 27 essentially make the same provisions across veterinary medicines and medical devices, and I do not intend to rehearse the arguments. On medical devices, surgical matters was a good example. There is the potential for life-changing and wonderful things, but also the real potential to do harm. We want to know that with every hip, breast, knee—whatever it is that is done—safety is paramount. Amendments 22 and 23 seek to create a special place for patient safety. I hope that the Minister will accept them.

Jo Churchill: First, patient safety is paramount. That is where I began my journey into Parliament. In my case, it was access to cancer drugs—something close to my heart. With regard to Orkambi, I understand and share the frustration felt by everyone. My heart goes out to those affected, who are very often parents. The cystic fibrosis campaign has, I think, a 98% sign up of all parents who have had children with cystic fibrosis. On their fight for Orkambi, I am sure everybody feels sympathy for them, because it took so long to provide access.

Drug companies have a responsibility here. This refers slightly to the comments the hon. Member for Nottingham North made about life science sectors or pharmaceutical companies all being large. The drug companies have a responsibility to price their drugs responsibly in a way that reflects the benefits that they bring to patients. I feel that the arrangements that we have in place in the National Institute for Health and Care Excellence and the cancer drugs fund have helped people to get access to medicines rapidly. There is still work to do, but they need to be marketised at a fair price. We made a commitment in our manifesto to establish an innovative medicines fund to address slightly some of the points that he made.

Amendments 22 to 27 relate to the three considerations the appropriate authority must have regard to when making regulations in relation to medicines for human and veterinary use and medical devices. The effect of the amendment would be to remove the requirement to have due regard to the attractiveness of the UK as a place to market and develop these products, and to assert the primacy of patient safety above all other considerations.

The safety of patients and the environment, people and animals—when moving into the area of veterinary medicine—absolutely underpins the regulatory decisions that are made. It is absolutely the case that we would never seek to make a regulatory change that puts somebody's health at risk; that would be counter-intuitive. However, I do not think that patient safety or safety in general is in conflict with the other considerations that these amendments are intended to affect.

The purpose of the regulation is to ensure that we do what is in the best interests of UK patients, or the veterinary sector when it comes to animals, so that they receive the best possible treatment without undue impact on the environment. It is likely that having a dynamic

[Jo Churchill]

and innovative market, where treatments or technologies are developed in the UK, contributes to the overall benefit of the patient, as those treatments will become available to them. These are not binary principles where regulation works only in the interests of one or the other.

The hon. Member for Nottingham North mentioned Nottingham—I also shout out to Cambridge, which is just down the road, and London, which the hon. Member for Bethnal Green and Bow mentioned. This country's life sciences sector is envied. The Government have committed to supporting it through the life science industrial strategy, in which we have sought to address the challenges faced by the industry and provide an environment that encourages companies to start and grow. All large companies start somewhere, and the hon. Member for Nottingham North knows that in the incubators around Nottingham, Cambridge and even my constituency of Bury St Edmunds, lots of small firms are working on the most incredible things to help patients.

Rushanara Ali: Nobody doubts that innovation will thrive if there are proper frameworks and safeguards in place, but it is clear that, in a post-Brexit world, our Government will want to see more innovation in research and development and investment, and sometimes the choices will come into conflict. There will be a trade-off, and we must ask what is a greater priority. Frankly, in recent years, some of the narrative that we have heard from the Government has not inspired confidence. I am looking for a very clear message that public safety will be set in stone. It is not good enough for Ministers to give reassurance; it has to be set in stone. We have to have confidence that public safety will not be compromised in the interest of getting investment. That is necessary, but it should not come at the cost of public safety.

Jo Churchill: I thank the hon. Lady for her intervention. The reason why the safety of human medicines is listed first is because safety is the paramount objective in everything.

In the life sciences industrial strategy, we have sought to address the challenges faced by the industry, provide an environment that helps companies to grow, and support collaboration between the NHS and industry better to adopt innovative treatments and technologies. Life science is one of the most productive and strategically important parts of the UK economy—it is worth more than £74 billion per annum—and we wish to cement our position as a world leader in that field to allow patients to benefit from cutting-edge treatments as soon as possible. The Bill is a key part of that, and it also keeps safety right at the top of the agenda. It is therefore right that, when we make regulations, the appropriate authority considers their impact and looks at whether they would constrain companies from seeking to bring new and innovative medicines or medical devices to market.

The concern of the hon. Member for Nottingham North is that the consideration of the UK's attractiveness, if applied, would mean a reduction in regulation on the sector, such that safety concerns would arise. That is simply not the case. I appreciate that he would like clarity on how the attractiveness consideration would work in practice, and the hon. Member for Central Ayrshire quizzed me about that too. The consideration would not mean reduced regulatory barriers to manufacturing, for example, as that would be to the detriment of patient safety. No! We have not sought to define attractiveness in the Bill, because the definition is as it is in ordinary language. There is no hidden or nefarious intent here. We want the UK to remain at the cutting edge of medical advancement, and that is done by recognising that the pharmaceutical industry benefits patients by making innovative therapies available through clinical trials and bringing them to market, or, indeed, collaborating in the event that expedited access to treatments is necessary.

12.15 pm

The pharmaceutical industry—and I am sure the hon. Member for Nottingham North will have seen the comments—has generally welcomed the attractiveness consideration as a factor in making regulation, as reflecting the UK's commitment to the sector as a whole. We have fantastic scientific research in the UK, as we will discuss when we turn to later amendments dealing with the development of medicines. We have the additional benefit of the NHS, and thus access to patients, and we have the funding to back up the aims. The benefit of a working relationship with industry is reflected in the work we have done to respond to the covid crisis, as the Association of the British Pharmaceutical Industry indeed highlighted in its evidence on the Bill. I hope that that reassures the hon. Gentleman that there is nothing nefarious in that term "attractiveness", but that we merely want to stimulate, to have the most vibrant sector and to ensure that we get innovation and drugs to patients as swiftly—but as safely—as possible.

Similarly, with regard to med devices, we have put in place additional directives in guidance documents drafted to support the changing approach, including requiring device manufacturers whose products utilise tissues of animal origin to ensure that there is adequate risk management, and that there are controls to prevent the spread of certain animal-borne diseases to users of their products, which is what the hon. Member for Nottingham North would expect. It is right that the regulation is made with regard to those affected by it, and that we strike the appropriate balance, where regulation protects the patient but ensures that patients get access as early as possible—an aim that I am sure we would both agree on—by ensuring that the UK market is a place where the life sciences sector wants to bring innovations to market. With respect to veterinary medicines, it is in the UK's best interest to ensure that effective medicines are available to treat animals and that we have access to the best possible veterinary medicines as companies bring them to the UK market.

We would expect the experts consulted as part of the process of making regulations under the Bill to give their views, and the Secretary of State or the relevant Northern Ireland Department to reach conclusions on the basis of that evidence. If evidence was supplied, as part of the statutory requirement to consult, that a regulatory change would affect patient safety, I would seriously doubt that any decision maker would proceed with that change. The Secretary of State made it clear on Second Reading that patient safety is of paramount

importance. Nor would Parliament allow such a change to be made, in all honesty. Innovation and safety are not mutually exclusive, and we want to continue to ensure that our regulatory framework facilitates the furtherance of both a vibrant sector and patient safety, at its heart. We do not want to risk delaying patients' access to potentially life-changing technologies, which would have consequences for their health and their safety.

The consideration that amendments 22, 24 and 26 would remove is intended to ensure that we take into account the full spectrum of impacts that regulation will have, and to ensure that patients get access to the most innovative treatment as the UK's regulatory model encourages development of new therapies and medicines. That is in itself intended to improve patient outcomes. Doing what is in a patient's best interest is at the heart of the Bill. Therefore there is no need for amendments 23, 25 and 27, as we see patient safety not as in conflict with innovation but as complementary to it. On that basis I ask the hon. Gentleman to withdraw the amendment.

Alex Norris: It feels to a certain extent as if we are having this conversation the wrong way round. I have not been in Parliament very long, but I have been on quite a few Bill Committees—I am sad like that. Normally the Opposition try to put words in a Bill and the Government say, "We agree with the principle; it just does not need to be on the face of the Bill." It feels as if on the attractiveness point we are doing that the other way round. I completely accept that there is no nefarious aim, but I personally think that it is superfluous. We can perhaps pursue that at a later stage.

I agree, too, that those things are not necessarily in conflict but, as my hon. Friend the Member for Bethnal Green and Bow said, I can see circumstances in which they might be, in the sense of pressure to drop our standards in order to get certain investments. For the Opposition, that has been a fear throughout, and we can certainly see it in this place, which is why we would like to enshrine a provision in the Bill.

Finally, I accept the point that patient safety must come first, but I do not think that the Bill—although it was written with lots of lists in it—creates hierarchies in those lists. It does not specify what falls down, that A is better than B which is better than C which is better than D, so that does not quite cover the point. I will not press the amendments to a vote, but with permission, we might come back to them later. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 1 ordered to stand part of the Bill.

Clause 2

Manufacture, marketing and supply

Ms Marie Rimmer (St Helens South and Whiston) (Lab): I beg to move amendment 1, in clause 2, page 2, line 23, at end, insert—

"(o) the origin and treatment of human organs used in the process of developing or manufacturing medicines".

This amendment empowers the appropriate authority to make provisions on the process of developing or manufacturing medicines in relation to the origin and treatment of human organs.

It is a pleasure to serve in Committee under your chairmanship, Mr Davies.

The purpose of the amendment is to empower the Government to make regulations providing for the treatment of human organs in the development of the manufacturing of medicines. This is necessary due to the actions of the Chinese Government in Beijing.

The China tribunal launched the first independent legal analysis of all evidence related to organ harvesting in China. The tribunal is headed by Sir Geoffrey Nice, QC, who served as the lead prosecutor of Slobodan Milošević. It stated:

"Forced organ harvesting has been committed for years throughout China on a significant scale".

I have forwarded copies of this document to all members of the Committee. I am trying to be as transparent as possible—this is not about trying to kid or trick on our commitment. I am sure that people in the country would agree. All members have copies, which I sent out over the weekend. I have given a short version of what the independent public tribunal said. Clearly, on the second page, it stated:

"Forced organ harvesting has been committed for years throughout China on a significant scale and that Falun Gong practitioners have been one—and probably the main—source of organ supply. The concerted persecution and medical testing of the Uyghurs is more recent, and it may be that evidence of forced organ harvesting of this group may emerge in due course.

The Tribunal has had no evidence that the significant infrastructure associated with China's transplantation industry has been dismantled and absent a satisfactory explanation as to the source of readily available organs concludes that forced organ harvesting continues till today."

There is therefore clear evidence that China is conducting medical testing on organs forcibly harvested from Uighurs, the Falun Gong, conscientious objectors and political prisoners. Indeed, a study by medical journal *The BMJ* raised ethical issues about more than 400 Chinese medical studies. The harvesting of organs from those people not only is an abhorrent act in and of itself, but often involves forced brain damage and vegetation of the person involved, of course leading to their eventual death.

Those papers that I sent to all Committee members refer to a debate in the House of Lords on 2 March, which raised the issue of the tribunal on forced organ harvesting in China. On that harvesting, Lord Alton commented that the

"organised butchery of living people compares to 'the worst atrocities committed in conflicts of the 20th century', including the gassing of Jews by the Nazis and the Khmer Rouge massacres in Cambodia".

The UK Foreign and Commonwealth Office informed the UK House of Lords that the World Health Organisation, which previously advised that China's transplant system is ethical, responded:

"The evidence that it uses is based on the self-assessment made by the country that is a signatory, and in this case that is China."

That comes from the UK Foreign and Commonwealth Office. The British Medical Association calls on the Government to reconsider their position on this issue in the light of the findings of the tribunal, and to use their influence with the international community to ensure that a full, proper investigation takes place.

We therefore need to take the necessary steps to protect the United Kingdom's healthcare system from being morally compromised through an injection of Chinese medicines developed in a way that breaches some of the

[Ms Marie Rimmer]

most basic human rights. This amendment does not aim to shut down trade in medicines between the United Kingdom and China. Leaps in progress made for preserving human rights should be readily shared and traded across the globe. However, these leaps in progress should not come at the expense of innocent human lives, and we must do all that we can to ensure that this practice cannot be profited from.

By passing this amendment, the Government will be empowered to make regulations ensuring that medicines supplied in the United Kingdom meet basic human rights standards with regard to how organs have been obtained in their development and manufacture. Any medicines that meet these standards and any other standards set by the Government will, of course, be welcomed into the United Kingdom.

This amendment does not force the Government to implement these regulations now; it merely empowers the Government and the relevant authorities to take the necessary steps to regulate around this issue when they are prepared to do so. I can therefore see no moral or practical reason why members of the Committee would not wish to see this amendment added to this Bill, and urge the Committee to consider it.

Alex Norris: My hon. Friend has made a persuasive and powerful case, as she did on Second Reading. From the debate on Second Reading, I took away the phrase that this gives us a chance to "strike a blow" against this heinous industry. I certainly support her in that regard.

Jo Churchill: I thank the hon. Member for St Helens South and Whiston for raising this issue and the pack that she so diligently sent to us all over the weekend, which I read with great interest. I know she holds this issue dear to her heart and she is passionate about it. I fully understand the intention behind the amendment. It is absolutely right that medicines that enter the UK supply must not have been manufactured or developed to using organs or human tissues that do not come from authorised sources.

I can assure the hon. Lady that safeguards are in place to provide surety on these issues. The requirements around the donation, procurement, testing, processing, storage and distribution of organs, tissues and cells intended for human application are set out in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Tissue Act 2004, which are separate from measures on medicines manufacture.

Medicines legislation already ensures that human tissues and cells used in the manufacture of medicinal products must meet those requirements. Safeguards are in place in those Acts to ensure that the appropriate quality, safety and origin of human tissue is known—for example, consent and traceability requirements apply to any human tissue or cell component imported into the United Kingdom and used as a material in the manufacture of a medicinal product. Importantly, a researcher is not able to conduct research on human tissue in the UK if they cannot provide evidence that it has been obtained ethically and in accordance with legal requirements. The Government will ensure that, under the new deemed consent arrangements for organ donations, donations of cells for advanced therapy and medicinal products cannot happen without expressed consent.

12.30 pm

The Bill is designed to ensure that we can update legislation to maintain an effective regulatory regime for medicines, clinical trials and devices. I want to assure hon. Members that the Bill as drafted includes a power in relation to the requirement that must be met in the manufacture of medicines under clause 2(1)(b), and in relation to clinical trials for the development of human medicines under clause 4. Such powers will enable us to update, as needed, the regulatory requirements in these areas to protect patient safety and to ensure the UK complies with international good clinical practice standards, including ethical considerations as set out in clause 4(1)(b). However, I am happy to commit to write to the hon. Member for St Helens South and Whiston on the reviewing of the FCO position, to which she alluded during her speech.

I trust that hon. Members agree that the amendment is not appropriate for the Bill—however well meaning—and that it is unnecessary, given the way in which medicines and medical devices are regulated. To that end, I respectfully ask the hon. Member for St Helens South and Whiston to withdraw the amendment.

Ms Rimmer: I am sorry about this—really sorry—because I understood that being a Minister was about co-operation, patience and morals. I do not disbelieve what the Minister says. However, there has been a public and independent inquiry, which found beyond all reasonable doubt. Those running the inquiry were people of stature and good regard, with a history of working for human rights.

I cannot withdraw the amendment. I ask that, at the very least, the Committee considers meeting Sir Geoffrey Nice and a Chinese surgeon who was forced to carry out the removal of organs in China, and who is now a taxi driver in London. They could meet somehow—I am sure we could do it on Teams or something like that. Before we get to Report, I urge the Committee to agree to such a meeting or to listen to and read the evidence. I cannot in all conscience accept that the learned people who sat on the China tribunal would have not researched and challenged—people such as Lord Alton, Lord Hunt and others in the House of Lords. Indeed, many hon. Members spoke about China's treatment of Uighur Muslims in a Westminster Hall debate that was led by a Conservative Member on 11 March. I am sure some of them would have looked and questioned.

I will not and cannot withdraw the amendment, but I urge the Committee to have neutrality and meet the relevant people so that we can check. I would certainly have to check with learned people before I can begin to consider withdrawing the amendment. I cannot accept that the learned people who have engaged with this issue for so long—we have worked on it for nearly two years and, coincidentally, the Bill came along. I have tried to get a private Member's Bill but have not succeeded. I have tried every nook and cranny to do anything I can to stop this practice. I do not want to risk our health service or our country's reputation, which could be tarnished by being involved. I have dear friends who are Chinese, but I do not trust the Chinese Government in

any way. I urge the Minister please at least to let us meet and consider this issue before Report. I have not sat on a Bill Committee before, Mr Davies, so I am not sure of procedure and, as you know, I am profoundly deaf. I urge the Minister please not to throw out amendment 1 without us doing that and rechecking every nook and cranny.

Jo Churchill: I understand the hon. Member's passion for this area. As she said, she has tried to find every nook and cranny. I gently repeat that the Bill is not the right place for amendment 1, but I commit to writing to my Foreign and Commonwealth Office counterpart on this point and to exploring it further, if that would be of assistance to her. However, I say again that the Bill is not the vehicle for the amendment and I ask her to withdraw it.

Rushanara Ali: I welcome the Minister's offer to write to the Foreign Office, and I commend in particular my hon. Friend the Member for St Helens South and Whiston for what she said. I have worked on human rights issues for other at-risk groups and there is a sense of concern about the position we may inadvertently find ourselves in. Will the Minister, in addition to writing to the Foreign Office, commit to ensuring that there is a review within Government to ensure that our safeguards are up to date? While I accept that the legislation is there, some gaps may need to be addressed and, if they cannot be addressed by the Bill, we need to find a way to assure ourselves that we have all the right safeguards in place. That will require a Health Department lead working with the Foreign Office and others.

Jo Churchill: As I said, I am willing to write to the Minister for Asia and the Pacific to explore this matter further, but I am afraid at this point that is all I can commit to.

Neil O'Brien (Harborough) (Con): The hon. Member for St Helens South and Whiston made a hugely important and impassioned point, and I strongly support her. Will the Minister undertake to circulate her letter to members of the Committee?

Jo Churchill: Yes, of course, I will be happy to inform the Committee when I write to the Minister for Asia and the Pacific, if hon. Members would find that helpful. We heard from the hon. Member for St Helens South and Whiston, and I am sure we all read the pack she sent at the weekend about the trade in human organs, which is truly heinous.

The Chair: The hon. Member for St Helens South and Whiston said she was inexperienced in Bill Committees. I can happily tell her that at this moment in time she is in charge and it is entirely down to her whether she wishes to press her amendment to a Division or to withdraw it. It is for her to indicate which of those options she would prefer.

Ms Rimmer: Thank you for your guidance, Mr Davies; it is much appreciated. I will not withdraw the amendment.

Question put, That the amendment be made.

The Committee divided: Ayes 5, Noes 9.

Division No. 1]

AYES

Ali, Rushanara	Western, Matt
Norris, Alex	
Rimmer, Ms Marie	Whittome, Nadia

NOES

Browne, Anthony	Fletcher, Katherine
Churchill, Jo	O'Brien, Neil
Davies, Gareth	Robinson, Mary
Double, Steve	Throup, Maggie
Everitt, Ben	

Question accordingly negatived.

Question proposed, That the clause stand part of the Bill.

The Chair: With this it will be convenient to discuss the following:

New clause 2—*Report on medicines under development*—

'On the date on which this Act is passed, and once every twelve months thereafter, the Secretary of State must lay before Parliament a report detailing what medicines the UK Government are developing.'.

This new clause requires the Secretary of State to lay before Parliament a report covering medicines that the UK Government are developing.

New clause 4—*Antimicrobial Resistance*—

'(1) The Secretary of State must regard antimicrobial resistance a priority in the development of new medicines.

(2) The Secretary of State must, within 12 months of this Act receiving Royal Assent, lay an updated report before Parliament setting out a UK-wide strategy for tackling antimicrobial resistance.'.

This new clause requires the Government to prioritise tackling antimicrobial resistance and produce an updated report setting out how it shall do so.

Jo Churchill: The clause allows for changes to be made to the law relating to the manufacturing, marketing and supply of human medicines. It provides an exhaustive list of matters on which amendments can be made by regulation, giving clarity and limits on what may be done by secondary legislation. I will take each subsection in turn as these are important areas for the Committee's consideration.

Subsection (1)(a) provides that changes may be made to update regulations in relation to manufacturing to reflect advances and innovation in the way in which medicines are prepared. That will enable us to take a revised approach to regulation, ensuring that regulations do not become barriers to patient access and to medicines manufactured in new ways while maintaining high regulatory standards to protect patient safety.

Subsection (1)(b) allows for changes to be made to the law governing the import of human medicines. It will support the continued ability to ensure that imported medicines are safe. We also want to be able to ensure that no unnecessary additional burden is placed on companies so that the UK remains an attractive place to supply medicines while protecting patients.

Subsection (1)(c) allows for changes to be made to the law governing the distribution of medicinal products by way of wholesale dealing. A wholesale dealing authorisation is required to supply or sell human medicines to anyone other than the patient using the medicine. In

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the light of any emerging safety concerns or innovative new techniques or technologies, changes may be required to maintain the quality of, and ensure proper distribution of, medicinal products. That could include such matters as providing and maintaining staff, premises equipment and facilities for the handling, storage and distribution of medicinal products under a wholesale dealer's licence as are necessary.

Subsection (1)(d) provides that changes may be made to the law relating to marketing authorisations for human medicines. We want to ensure that UK patients have access to high-quality medicines and new treatments, so we need a regulatory system that maintains and enhances the UK's attractiveness as a place to market novel and generic medicines while ensuring that medicines are safe and efficacious. We could, for example, amend the current regulations to offer additional statutory rewards or incentives for a certain type of application for a marketing authorisation, which would encourage new medicines to continue to come to the UK in a timely fashion.

Subsection (1)(e) allows for changes to be made to the law governing the manufacture, import or distribution of active substances. An active substance is an ingredient used to make a finished medicinal product and gives medicine its therapeutic effect. The ability to amend and update regulations in relation to active substances is necessary to protect public health, because if there is not adequate control of an active substance, contamination can carry over to the finished medicinal product. The ability to change the rules governing active substances means that we can update the UK regulations to react in response to emerging public health risks resulting from issues relating to active substances and ensure continued supply.

Subsection 1(f) allows for changes to be made to the law governing the brokering of human medicines. The brokering of medicinal products consists of negotiating independently and on behalf of another person in relation to the sale or purchase of medicinal products. We need to be able to amend the rules governing brokering in response to any new industry practices that arise and risk infiltration of the supply chain with falsified medicines. We could use this provision to restrict such activities, thereby securing the medicine supply chain and reducing the risk to patient safety.

12.45 pm

Subsection (1)(g) enables regulations to be made to amend the requirements on the registration of the premises of pharmacy businesses. While separate provisions cover the regulation of other parts of the supply chain, such as manufacturing and wholesaling, this provision would enable us to amend requirements regulating retailers, mainly retail pharmacy businesses and pharmacy premises, which goes back to the point made by the hon. Member for Nottingham North in the discussions about clause 1. This is necessary to maintain coherent regulation of the whole supply chain for human medicines, but also ensures that the UK has the power to keep the regulation of pharmacies up to date.

Subsection (1)(h) enables regulations to amend or supply the requirement around recording information about the supply of human medicines, ensuring the UK has the ability to amend existing record-keeping requirements. That is hugely important for the interest of patient safety as future models of supply evolve.

Subsection (1)(i) provides that amendment can be made to the law that governs the requirements for reporting safety data about medicines on the UK market. This will support continued improvement of pharmacovigilance in the UK to protect patient safety.

Subsection (1)(j) provides that amendments can be made to the law governing the labelling and packaging of medicines, and the information that must accompany them. This will enable innovation in the way in which information is provided alongside medicine. Patients may find digital routes to packaging information more accessible than paper copies. This subsection could enable us to require both paper and digital versions to be available. We have published an illustrative SI to show how this amendment could be made in regulations.

Subsection (1)(k) provides that amendments can be made to the law relating to the advertising of human medicines. Having the ability to make changes to the regulation of the advertising of medicines would enable the Government to ensure that advertising requirements can be updated to reflect developments in areas such as digital communication channels, while ensuring that patients and healthcare professionals continue to receive good information about the medicines they may use or prescribe. This would help ensure that the UK remains an attractive place to market such medicines.

Subsection (1)(l) relates to the supply of medicines online and would enable the UK to introduce and amend a bespoke national registration scheme for online sellers of medicines, and replace the EU distance-selling logo that is currently used. We have published an illustrative SI to show how the provision for a national scheme could be made. It is essential that there are appropriate protections in place to ensure the safety of supply of medicines online.

Subsection (1)(m) outlines the regulatory provision that may be made in relation to the requirements that need to be met for a prescription to be valid. For example, this might be used to update the particulars that must be included in a prescription or the types of products for which electronic prescriptions are valid.

Subsection (1)(n) deals with amendments made to the provisions that govern who can supply or prescribe human medicines. The provisions referred to are set out in subsection (2). The power gives the Government the ability to amend the rules around who can supply, administer and prescribe medicine in line with healthcare needs, where it is safe and appropriate to do so. The most recent change to prescribing responsibilities was in 2018, when legislation was amended to allow trained paramedics to act as independent prescribers. We have published an illustrative SI showing how the provision can be made to permit dental hygienists to supply and administer certain medicinal products in the course of their professional practice.

Alex Norris: I am conscious that our carriage will turn into a pumpkin shortly, so I will move with some tempo.

New clause 2 is the Porton Down clause, and the world has changed greatly in the last few months. We now know, in a way we could never have grasped before,

how an air-borne virus can lock us up in our homes for months on end, and even longer for many. We also know that what happens on the other side of the world can be with us quickly, and that at times, as with the current coronavirus, there is not much we can do about that.

We ought to reflect on what we are doing at home. We have reached a point where we could have a greater public understanding and scrutiny of the sorts of things being developed in our name by our Government. Porton Down is a world class facility full of incredibly talented people serving our national interest, but we do not know what they do. We get snippets. We know that in the past decade they have experimented on 52,00 animals, which is six times the rate of any other UK lab. I have absolutely no idea whether that is too high, too low, or just right, because we do not know. I am trying to probe the ways in which we can get greater transparency about what potentially life-saving or possibly life-ending products are being developed on our doorstep. If the Minister thinks there are better ways to do that, I am happy to consider those. The drafting does not refer to everything developed in the UK, but things developed by the Government. It is behind closed doors, very secretive, and potentially quite dangerous, so I am keen to know how we might get greater scrutiny.

New clause 4 on antimicrobial resistance is a passion of my predecessor, my hon. Friend the Member for Washington and Sunderland West. It is topical now as we wrestle with a horrendous virus, and I express my solidarity with the Minister and her colleagues on their efforts in doing so. Clearly, microbial organisms can adapt and have an incredible impact, as we are seeing. They can also disrupt much more conventional matters such as the antibiotics that are crucial for transplants and chemotherapy. It is laudable that the Government have a 20-year vision for this, although I hate long strategies. What is done in year one is much more important than what is done in year 20. I know there is a five-year plan sitting behind that, but even that feels too long a time. The new clause gives the opportunity instead for an annual report, which would be an improvement. If that is not the right vehicle, how might we be able to play our role in the conversation around antimicrobial resistance, and how do we get an appropriate period in which to hold the Government to account to ensure that we make progress?

Jo Churchill: I am grateful to the hon. Gentleman for raising the development of new medicines in new clause 2, which are important in new clause 3 as well. Antimicrobial resistance, as he has mentioned, is an absolutely critical issue of today. I will first set out what we are doing in that area. The development of medicines is an integral part of the UK life sciences sector, and we are committed to making sure that we can develop such medicines. The Bill gives us powers to maintain an effective system for regulating, including with respect to clinical trials. New clause 4 allows us to adapt the regulatory framework around them in a way that best suits the industry. The development of medicines is the role of the pharmaceutical industries and researchers, and we want to support them fully. The Government are committed to supporting a thriving sector, investing more than £1 billion a year in health research through the National Institute for Health Research, which is committed to openness and transparency about where the funds go. It ensures that all trials publicly register before any patient intervention, and key trial outcomes are made publicly available. However, the arrangements for Government support and funding through trials is not within the Bill.

I will address some of the work that the hon. Member for Nottingham North alluded to at Public Health England's Porton Down campus, sometimes referred to in the context of medicine developments. The current PHE facilities at Porton Down do not develop medicines for Government, but engage in a range of scientific work for commercial and public sector customers. This includes the safety and efficacy of testing vaccines and therapeutics, and discovery work relating to novel and dangerous pathogens. Porton Down is also the site for work by Porton Biopharma Ltd, which is a public non-financial corporation and is outside central Government. Although PBL develops and manufactures biopharma products, this falls outside the Government and we are therefore not in a position to publish reports on the development of its work.

The hon. Gentleman also raised the important issue of AMR in new clause 4. I want to reassure the Committee that tackling AMR is a high priority for the Government and that its impact remains on the national risk register. The UK continues to lead the way on global action to tackle AMR, working alongside international partners, the most famous of whom is probably the most recent chief medical officer before Professor Sir Chris Whitty, Professor Dame Sally Davies, who has taken up her position as the special envoy for AMR. Her role will continue to underline the UK's position as a world leader in developing and delivering international action in that space.

In January 2019, the UK Government published their vision to contain and control AMR by 2040. Achieving that is supported by the delivery of a five-year national action plan from 2019 to 2024. The delivery of the cross-Government commitments in the action plan is being overseen by a joint DHSC and Department for Environment, Food and Rural Affairs-chaired programme board, established in October 2019. The commitments in the national action plan cover all sectors, including human health, animal health, food and the environment.

The UK has already made good progress in reducing its use of antibiotics in humans and animals, and we now have the fifth-lowest level of antibiotic consumption in food-producing animals out of 31 European countries. We have also seen unprecedented levels of investment in collaboration in research on AMR nationally and globally. The UK invests significantly in AMR through the Fleming Fund and the global AMR innovation fund.

The hon. Member for Nottingham North is correct that the Government should prioritise the development of new medicines to address antimicrobial resistance, including antibiotics. Indeed, we already do. Having a pipeline full of antimicrobial drugs is critical to our efforts to contain, control and mitigate AMR, as outlined in the strategy towards 2040.

In July 2019, the UK formally launched a project for developing and testing the world's first subscription-style payment model for antibiotics. If successful, it would mean that pharmaceutical companies received payment up front for access to their antibiotic products, based on the products' value to the NHS, as opposed to the

[Jo Churchill]

volume used. We are the first country in the world to test such a model and more information will be published on it in due course.

Although we know how important new medicines are in tackling antimicrobial resistance, a strengthened focus on prevention and the control of infection will help to contain the emergence and spread of resistance to antibiotics. By limiting and reducing the need to use antibiotics in the first place, we are taking a zero-tolerance approach to avoiding infection in human healthcare settings, as set out in the action plan. Our plan will result in at least 15,000 fewer UK patients being affected by infections each year by 2024, and 5,000 fewer drug-resistant infections.

In parallel, we are focusing on reducing animal exposures and susceptibility to pathogens that could result in the need for treatment with antimicrobials. By working closely with the veterinary profession to implement those preventive measures, we will reduce the need for new antimicrobial medicines as we reduce them in the food chain.

I hope that hon. Members will agree that the UK Government are working hard to ensure that AMR is controlled and contained through the vision for 2040 and the five-year action plan. New clause 4 is not necessary for the Bill. If the hon. Member for Nottingham North has further specific questions in relation to either medicines by the Government or AMR, I would be happy for him to write to me and I will endeavour to answer those points in a closed format. On that basis, I ask him to withdraw the new clause.

Alex Norris: I do not intend to press new clauses 2 and 4 to a Division. The Porton Down answer was helpful. In the terms of the amendment, it is not necessary, but I will have to work out how to get from accepting the principle about not developing medicines to accepting the next sentence about testing vaccines. That is a distinction without a difference, but I accept that it would not quite work in the Bill. The answer about the limited company does not hold either. As a wholly owned subsidiary of the UK Government, I think we could take an interest in that.

I was grateful for the detailed answer about AMR. I will take up the offer of engaging directly as and when. To be clear, we are keen to engage on that, because it is a significant issue and we want the Government to succeed at it. I hope that can be part of an ongoing conversation about it. On that basis, I will not press the new clause.

Question put and agreed to.

Clause 2 accordingly ordered to stand part of the Bill.

1pm

Proceedings interrupted (Programme Order, this day).

The Chair then put forthwith the Questions necessary for the disposal of business to be concluded at that time (Standing Order No. 83D).

Clauses 3 and 4 ordered to stand part of the Bill.

Adjourned till this day at half-past Three o'clock.