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.

PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT
GENERAL COMMITTEES

Public Bill Committee

MEDICINES AND MEDICAL DEVICES BILL

Second Sitting

Monday 8 June 2020

(Afternoon)

CONTENTS

No proofs can be supplied. Corrections that Members suggest for the final version of the report should be clearly marked in a copy of the report—not telephoned—and must be received in the Editor's Room, House of Commons,

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

(Afternoon)

[Philip Davies *in the Chair*]

Medicines and Medical Devices Bill

3.30 pm

The Chair: As I mentioned this morning, I remind Members to respect social distancing guidance. I will intervene if necessary to remind people of that. I also remind Members that tea and coffee are not permitted in Committee sittings and to ensure that their mobile phones are switched off or switched to silent mode. Finally, the *Hansard* reporters would be very grateful if Members could email copies of their speaking notes to hansardnotes@parliament.uk.

Clause 5

Fees, offences, powers of inspectors

Alex Norris (Nottingham North) (Lab/Co-op): I beg to move amendment 11, in clause 5, page 3, line 39, at end insert—

"(1A) The Secretary of State must publish a fees regime within three months of the date on which this Act receives Royal Assent."

This amendment requires the Secretary of State to publish their proposed list of fees in respect of human medicines.

It is a pleasure to resume serving under your chairship, Mr Davies. We move to the rapid-fire round, which will almost inevitably lead to me at some point giving a speech to a previous or future amendment—I am sure colleagues will be gentle and generous with me when I do so. This short probing amendment relates to fees in the discharge of the human medicines sphere. The principle is that, in the exercising of clause 1(1) it is conceivable that the Secretary of State, the Department and the Government in general will incur costs, so clause 5(1)(a) allows for provision to be made to exercise a function to charge for that, which makes perfect sense.

The Medicines and Healthcare Products Regulatory Agency has previously worked on a cost recovery basis, which makes a lot of sense, but the amendment is designed to test whether it would not be better to have a comprehensive, clear and consistent fees regime. The MHRA and the Government in general have a tough job against a potential occasional big foe in the pharmaceutical industry—or big partner to work with, at least. I assume, but would like to hear from the Minister on the record, that the expectation is that there will be equal pay for an equal job, so a bigger firm that is better equipped to lobby would not end up paying smaller fees than a smaller firm, simply because that firm was better at arguing or making its case. Is cost recovery still in general the preferred option? If so, might it not strengthen the Secretary of State's hand if that were put in the Bill?

The Parliamentary Under-Secretary of State for Health and Social Care (Jo Churchill): It is a pleasure to be back this afternoon. I am grateful to the hon. Member for raising the important issue of fees in his amendment, and I recognise the intent of that probe. I am sure we agree that it is important that all new fees for human medicines are set in an open, fair and transparent way. I want to reassure him that what the amendment seeks to achieve is already standard practice and is happening. I will rapidly set out the steps already in place to ensure the fairness, openness and transparency that underpin the fees regime for human medicines.

The current fees have been subject to consultation and are provided for in legislation. They are published online and publicly available at gov.uk. All of that is supported by a formal and standardised process for reviewing existing fees and for the introduction of new fees for human medicines. The standard approach for setting statutory fees is full cost recovery, as the hon. Member alluded to, which means that fees must be set at a cost that reflects the activity involved in carrying out such a specific regulatory function.

The full cost recovery approach is set out by Her Majesty's Treasury in its "Managing public money" guidance, which ensures that the Government neither profit at the expense of consumers nor make a loss for taxpayers to subsidise. Therefore, fees cannot be set arbitrarily, and the fee must reflect the cost of the regulatory work carried out. I think that goes some way to addressing the hon. Member's probe on size.

Existing fees for human medicines are kept under active review by the Medicines and Healthcare Products Regulatory Agency. The amendment is specifically concerned with new fees that might be introduced under the powers in the Bill. It is already a requirement that new fee proposals are subject to consultation, and that duty continues for fee proposals under the Bill. We will publish impact assessments with the new proposals, which will set out the effects of any changes to fees in the UK on Government, industry or the general public. Her Majesty's Treasury will be engaged throughout the fee proposal process, and any proposals for new fees will be subject to approval from HMT. It is also standard practice for the MHRA to engage with industry and trade bodies through regular meetings to discuss any new fee proposals that might be coming up.

I trust my explanation has reassured the hon. Member for Nottingham North that the requirements are and will continue to be in place so that fees for human medicines are fair, open and transparent. I therefore ask him to withdraw his amendment.

Alex Norris: I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

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

Jo Churchill: Clause 5 provides that changes can be made to the law relating to human medicines with respect to fees, criminal offences and the powers of inspectors. Regulations made under clause 1(1) allow us to change the UK's regulatory framework for human medicines as science, technology and clinical needs evolve. When the regulatory regime is updated, it is important that the regulator—in this case, the MHRA—can continue to regulate effectively and maintain compliance with all elements of the regime. To ensure this, it may be necessary to make provision about charging fees, creating criminal offences, and updating inspectors' powers when making changes to the regulatory regime. Regulations made under clause 1 and relying on clause 5 will enable us to do this. We will consult before making any of those changes.

Clause 5(1)(a) allows us to make provision about the charging of fees. The regulator is self-funding for the purposes of medicines regulation. This work includes assessment for marketing authorisations and clinical trials of human medicines and inspections. It is funded by fees payable by the pharmaceutical industry in relation to the services and regulatory work provided. The current fees are set out in the Medicines (Products for Human Use) (Fees) Regulations 2016 and vary according to the specific areas of work.

It is important that existing fees can be amended, or fees can be introduced in connection with the MHRA exercising functions conferred by human medicines provisions as they evolve. Any proposal to introduce new fees is subject to consultation. The impacts on industry, Government and the general public would be evaluated through the usual process of an impact assessment. As part of its regulation of human medicines, the MHRA is able to impose criminal sanctions for certain regulatory breaches. As the regulatory regime is updated in future, it is important that we have the ability to also update the corresponding list of offences against which the MHRA can take action.

Clause 5(1)(b) allows us to create criminal offences with a maximum of two years' imprisonment to cover updated requirements to supplement the evolution of the regulatory regime. MHRA inspectors play a critical role in ensuring compliance so that medicines are safe and effective for patients, and so that manufacture, research and surveillance processes are carried out to recognised standards. Inspectors already have all the powers to enter premises at any reasonable time to determine whether there has been a contravention of medicines regulations. For example, they may take samples or copies of documents if it is suspected that an offence has been committed. We have published two illustrative statutory instruments to demonstrate how provision can be made in regulations, relying on clause 5(1)(b) in combination with subsections of clause 2, to create a criminal offence for failing to comply with the new requirement set out in the regulations.

Clause 5(1)(c) allows us to update the relevant powers of entry and other powers of inspectors to align with new elements of the regulatory regime as it evolves. I commend the clause to the Committee.

Question put and agreed to.

Clause 5 accordingly ordered to stand part of the Bill.

Clauses 6 and 7 ordered to stand part of the Bill.

Clause 8

Power to make regulations about veterinary medicines

Alex Norris: I beg to move amendment 12, in clause 8, page 5, line 17, at end insert "services."

This amendment broadens the range of issues that the Secretary of State must consider to include access to the relevant services to dispense veterinary medicines.

I did not want us to miss out the veterinary medicines part of the Bill, because it is important. We are a nation of animal lovers and we are keen that the laws we make are sympathetic to all living beings. The issue was also raised on Second Reading, because it has an impact on the food chain, so we must be mindful of setting an effective regime, as I know the Government are keen to do.

The amendment is simple. Again, I hope that it is redundant, but I want to test that with the Minister. There is a clear read-across between parts 1 and 2 of the Bill, which is that the powers being reserved for human medicines are largely the same as those being reserved for veterinary medicines. The word that I would like to be added in clause 8(2)(b) after

"the availability of veterinary medicines"

is "services", because one way in which veterinary medicine differs from human medicine is that we do not have a universal service, so that access point is an important consideration for the Secretary of State.

I have not drafted the amendment elegantly enough. When we get to amendment 13, we will discuss something called the cascade, which was new to me until a couple of weeks ago. The principle of the cascade is that, whereas in human medicine we have expectations that certain medicines will be used to treat certain conditions and doctors do not have a massive amount of latitude to go outside that, in veterinary medicine, if such a thing is not available, the veterinarian can fall down the chain and use a different painkiller—perhaps a human painkiller. That is obviously important.

I wonder—and this is what I am testing with the amendment—whether that creates a possible inequity. If there is better access to veterinary medicines or supplies in certain communities, perhaps rural versus urban, that could create not a two-tier service, but a slightly different service from the one we want. It would therefore be useful for the Secretary of State to have regard to the services, as well as the physical ability to get pills, potions or whatever. That is all the amendment seeks to test and I am interested to hear what the Minister says.

Jo Churchill: I am grateful to the hon. Gentleman for raising the important issue of the availability of veterinary medicines. The intention is clear: to ensure continued access to veterinary medicine equitably for all the nations' animals.

The Bill provides the power to amend or supplement the Veterinary Medicines Regulations 2013, which cover the full supply chain of veterinary medicines from development to supply. The requirement for the appropriate authority to have regard to the availability of veterinary medicines, as set out in clause 8, therefore ensures that when making regulations under the clause, the availability of veterinary medicines throughout the supply chain is considered.

Although the intended effect of amendment 12 is to expand on those factors, the actual effect would be to inadvertently narrow their scope to focus only on the availability of veterinary medicines services, such as the dispensing of veterinary medicines, rather than the availability of veterinary medicines more widely and more equitably. Veterinary medicines services alone are not the determining factor in the availability of veterinary medicines.

Clause 8, as drafted, ensures that the appropriate authority must have regard to the availability of veterinary medicines throughout the supply chain, so that the rural versus urban comparison the hon. Gentleman used would not be a comparator and medicines would be equally available. I therefore ask him to withdraw the amendment.

Alex Norris: I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

3.45 pm

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

The Chair: With this it will be convenient to discuss new clause 5—*Capacity of the veterinary industry—*

"(1) The Secretary of State must, within 12 months of making regulations under section 8(1), lay a report before Parliament setting out an assessment of the capacity of the veterinary industry, relative to the requirements of those regulations."

This new clause requires the Government to make an assessment of the capacity of the veterinary industry.

Jo Churchill: Clause 8 provides the power to amend or supplement the Veterinary Medicines Regulations 2013. Subsection (1) gives the appropriate authority a power, by regulation, to make amending or supplementing provision within the scope of the matters set out in clauses 9 and 10. The appropriate authority may use this power only to build on—in other words, amend and supplement—the current regulatory framework for veterinary medicines. Clauses 9 and 10 set out an exhaustive list of matters about which regulations could be made on veterinary medicines. An in-depth explanation of those clauses will be shared with the Committee throughout the course of these sittings.

Subsection (2) sets out three matters to which the appropriate authority must have regard when making regulations under clause 8: the safety of veterinary medicines in relation to animals, humans—including consumers of produce from treated animals—and the environment; the availability of veterinary medicines; and the attractiveness of the relevant part of the UK to industry for developing or supplying veterinary medicines. Subsection (3) explains that

"the relevant part of the UK"

depends on where the UK regulations will apply. The environmental safety aspects could include considering the potential impact of veterinary medicines on terrestrial and aquatic eco-systems and their flora and fauna—for example, the environment can also be affected by slurry application and excretion by grazing animals.

Subsection (4) sets out the appropriate authority for the purposes of regulations made under clause 8(1). The appropriate authority able to exercise this delegated power for England, Scotland and Wales is the Secretary of State. For Northern Ireland, the appropriate authority is either the Department of Agriculture, Environment and Rural Affairs in Northern Ireland acting alone, or the Secretary of State and the Northern Ireland Office acting jointly. This means that the powers can be exercised on their own, as well as jointly on a UK-wide basis.

Alex Norris: I will speak briefly to new clause 5. I was happy to withdraw amendment 12, but the principle was about trying to ensure that there is equitable access to services, because that is how veterinary medicine differs from human medicine. New clause 5 follows that principle through to its logical conclusion. This may have been done; I have been looking but have been unable to find it. I am sure the Secretary of State for Health and Social Care has seen hundreds and hundreds of health equity audits: how are things in Nottingham different from in Shipley, and how does that impact on health outcomes? For all the reasons I mentioned at the beginning, I wonder whether it is the same in the veterinary industry and whether there are regional, rural-urban and north-south disparities that mean access is different. The potential fall-outs from that are worth considering.

The new clause is intended to probe and to see whether the Government have that sort of information. If so, maybe they could let us see it—either shortly or during the rest of the proceedings on the Bill.

Jo Churchill: I am grateful to the hon. Member for raising the matter of capacity within the veterinary industry as it stands, in order to provide equity throughout. I recognise that he has given us examples of north-south disparities and so on, and I recognise the good intentions behind the new clause and his desire to ensure that the veterinary industry is working to full capacity and in unanimity across the piece. We agree that vets are an essential part of our animals' lives and a key component of the UK system of protecting food safety, providing international assurance and upholding standards in welfare.

The Government are already working with various veterinary sector stakeholders, including the Royal College of Veterinary Surgeons and the British Veterinary Association, to understand the UK's veterinary resourcing needs and ensure that there are adequate numbers of vets in the short and long term. We are working with a variety of initiatives to build a sustainable, diverse and modernised UK veterinary infrastructure to ensure that we maintain access to the right people, with the right skills and knowledge, supporting food safety and animal health and welfare, as well as trade. DEFRA has successfully secured a place for the veterinary profession on the Home Office shortage occupation list, and we are grateful to the Royal College of Veterinary Surgeons and British Veterinary Association for their work on the issue. It makes it easier for veterinary employers to gain visas.

To turn to specifics, as Members will know, the Bill introduces a statutory duty to consult before making changes to the Veterinary Medicines Regulations 2013. That consultation duty, in clause 40, requires that the appropriate authority must, before making regulations, consult those it considers appropriate. That is the most suitable route for ensuring that all those in the veterinary industry who need to be consulted are included. We are working across Government and with the veterinary profession to help to develop a flexible, skilled workforce that meets UK needs and irons out disparity of service. I want to assure the hon. Member for Nottingham North that it is a key priority to enable an innovative, productive and competitive veterinary medicine sector that invests in its people and skills. To help to achieve that, we shall ensure that there is access to sufficient appropriately skilled labour to drive continued industry growth and productivity, while ensuring that the environment for humans and animals is safe.

Alex Norris: I appreciate that answer, and the detail in it. I guess the only way in which I would supplement my questions is to ask that, once the fruits of the work with the relevant stakeholder bodies are available, they should be shared. That would be of great interest to Members on both sides of the House.

Question put and agreed to.

Clause 8 accordingly ordered to stand part of the Bill.

Clause 9

MANUFACTURE, MARKETING, SUPPLY AND FIELD TRIALS

Alex Norris: I beg to move amendment 13, in clause 9, page 6, line 11, at end insert—

'(1A) The Secretary of State must by regulations make provision about the use of the Cascade."

This amendment gives the Secretary of State the responsibility to make provisions regarding the Cascade, a process where veterinarians can dispense different medicines to animals, such as human medicines, should appropriate conventional animal medicines not be available.

I have buried the lede, obviously, by talking about the cascade already; but I am interested to hear a little more detail about the Minister's vision for the cascade. It is obviously an entrenched principle across the European Union, and an industry standard. It has a significant impact on the lives of animals and, by proxy, humans as well. It seems to me an important principle, but it is not on the face of the Bill. The Government would, on Royal Assent, have the immediate ability to diverge away from the cascade quite quickly, but I wonder about the safety of that and whether that is in the Government's plans. It was not in the impact assessment, so I am keen to scope out whether we expect the cascade to continue to be a principle in this country, and, if so, whether we expect our cascade to reflect closely the one used by our EU counterparts.

Jo Churchill: A clause or so back, the hon. Gentleman gave us a snapshot of what a cascade is, and I do not think I could put it better. My notes say that veterinary surgeons can prescribe gabapentin, a human medicine, to treat chronic pain in animals, particularly if it is of a neuropathic origin, as there is no equivalent in veterinary medicine. As the hon. Gentleman said, the cascade is about making sure that there is something in the veterinarian's bag to enable appropriate care to be given to animals.

I am grateful to the hon. Member for Nottingham North and to the hon. Member for Central Ayrshire, who I think also signed the amendment, for raising the important issue of the prescribing cascade. However, not only is the amendment not necessary, but I argue that it could be unhelpful in certain instances. I recognise the desire to ensure that the use of prescribing cascades is regulated. The cascade enables veterinary surgeons to have access to a wider range of medicines to treat animals under their care and, in particular, to prevent the unacceptable suffering that might occur if they could not prescribe those alternatives.

The provisions with regard to the cascade are set out in schedule 4 to the Veterinary Medicines Regulations 2013 and the Bill already confers discretionary powers that would allow the appropriate authority to decide, following consultation, whether and how cascade requirements in the existing regulations might be amended in the future. That is provided for in clause 9(1), for the professionals to decide, arguably.

The amendment as drafted would appear to obligate the Secretary of State to update the regulations with regard to the cascade, as opposed to making those changes when it is appropriate to do so, and evaluate the cascade above other important aspects of the veterinary medicines regulatory framework. Although the cascade is important, it is our position that the regulations should be updated when it is clear and necessary to do so, rather than operating under a compulsion to do so for any one element, as putting it in the Bill might lead to. In that light, I ask the hon. Gentleman to withdraw it.

Alex Norris: I am happy to withdraw the amendment on that basis. The point of putting it in was to shoehorn the subject into the conversation, which was obviously effective. I did not hear from the Minister whether she felt that we are likely to continue to reflect the EU arrangements on that. Given that it is novel and specific to this area of medicine, and given that it is not risky, but diverges from what we consider basic medical practice in humans, it is of interest to people.

Perhaps now is not the moment to hear about the Government's plans to reflect, or not, the judgments made by EU colleagues in future, but I hope that, over time, we can continue to have that conversation because I think there is public interest in that. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

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

Jo Churchill: On amendment 13, I will write to DEFRA to seek clarification for the hon. Gentleman if that would be helpful. As we move through the Bill in the spirit of co-operation, I am more than happy to continue the conversation.

Clause 9(1) provides that amendments may be made to the Veterinary Medicines Regulations 2013 about the manufacture, marketing, supply and field trials of veterinary medicines. The Committee will note that in large part, clause 9(1) makes very similar provision to clause 2(1). I will take each subsection of clause 9(1) in turn.

Subsection (1)(a) sets out that the regulations made under the power in clause 8(1) may make provision about authorisations to manufacture veterinary medicines. The subsection means that it will be possible to update the rules around manufacturing authorisations—for example, to reflect the latest scientific advances in manufacturing and to address the manufacture of novel and innovative veterinary medicines. The subsection is therefore needed to future-proof the regulatory regime.

Subsection (1)(b) allows provision to be made about authorisations to import veterinary medicines, which is needed to continue to secure supply chains for those medicines entering the UK. By updating our existing regulatory framework, we can maximise the availability of veterinary medicines, while taking care that our approach does not place an additional burden on those who import medicines. Such a change can benefit animal owners, as it can lead to quicker access to veterinary medicines, a point that my hon. Friend the Member for Penrith and The Border brought up on Second Reading. We could use the subsection to allow additional professions, for example veterinary nurses, to import certain types of veterinary medicines with appropriate controls.

Subsection (1)(c) allows for provision to be made about authorisations to distribute veterinary medicines by way of wholesale dealing, which would ensure that we can provide further assurance on the quality and security of the full distribution chain for veterinary medicines. We could, for example, amend the application process for a wholesale dealer's authorisation, supplement the requirements that must be met by the holder of such an authorisation, or amend the exceptions to the requirements for an authorisation.

[Jo Churchill]

The subsection could also be used to change the requirements for a wholesale dealer's authorisation to cover new and novel products that may have new or additional storage and distribution requirements. That would maintain the quality and security of the distribution chain for such veterinary medicines and ensure that they are stored appropriately and safely throughout.

Subsection (1)(d) allows for provision to be made about marketing authorisations for veterinary medicines. This would help to ensure that the UK remains an attractive place for the pharmaceutical industry to bring to market both new and established medicines, and that UK animal owners do not have to wait for new, innovative or generic veterinary medicines. As an example, regulations could offer statutory rewards or incentives for certain types of applications for marketing authorisation.

4 pm

Subsection (1)(d), combined with paragraphs (a), (b) and (g), could also be used to make changes to the regulations about using an authorised medicine outside the terms of its marketing authorisation if there is clinical need and benefit. If there is no suitable veterinary medicine authorised in the UK to treat a condition in a species, a vet can treat an animal under his or her care in accordance with the prescribing cascade, which is where a medicine can be used to treat a disease outside of its authorisation or to treat a different species from those it is authorised for. The cascade is set out in the Veterinary Medicine Regulations 2013.

Subsection (1)(e) provides that regulatory provision may be made about manufacturing, importing or distributing active substances. This power could be used to ensure that the supply chain for active substances that are used in veterinary medicines remains secure. The quality of the active substance is critical to assure the safety, quality and efficacy of the finished veterinary medicine. Regulations could, for example, provide for a registration scheme for manufacturers, importers and distributors of active substances.

Paragraphs (f) and (g) allow for provision to be made about the categories of person who may supply veterinary medicines, and about the requirements that must be met in relation to the supply of these medicines. Proposals for new powers to supply or prescribe medicines will be carefully developed with the relevant professional bodies, such as the Royal College of Veterinary Surgeons, and will be subject to consultation. That reflects the Government's desire to make veterinary medicines as accessible as possible while not compromising animal safety or the safety of the person administering the medicine.

Subsection (1)(h) allows for provision to be made about the registration or accreditation of persons who sell or offer to sell veterinary medicines over the internet. The power could be used to make the voluntary UK-based internet retailer accreditation scheme mandatory, which could provide further assurance for UK customers and prevent customers from unwittingly buying illegal medicines. This power, in conjunction with clause 10, could also be used to enforce the scheme with appropriate sanctions, including the ability to suspend or revoke an online supplier's registration. It would also enable us to extend existing inspection powers and criminal offences in the regulations to cover any new scheme.

Subsection (1)(i) allows for provision to be made about the circumstances in which a veterinary medicine can be administered. Regulations could, for example, make provision restricting or prohibiting the administration of substances that adversely affect public health or consumer safety. Such regulations could be used to incorporate our priorities on antimicrobial resistance into secondary legislation—for example, through restrictions on the preventative use of antibiotics and provision encouraging responsible use of antibiotics.

Subsection (1)(j) allows for provision to be made about the notification and reporting requirements in relation to veterinary medicines that have been placed on the market. Regulations could be used to make provisions about the reporting of adverse reactions to veterinary medicines. Reporting is used to ensure that emerging risks in connection with a veterinary medicine are identified and acted upon as early as possible—for example, to make reporting requirements more proportionate and reduce unnecessary burden for the pharmaceutical industry.

Subsection (1)(k) allows for provision to be made about the labelling and packaging of veterinary medicines, or the information that must be supplied with them or made available in relation to them. It could, for example, be used to introduce pictograms on labels for veterinary medicines. Pictograms are standardised pictorial symbols for a word or phrase and could be used to replace or supplement some of the written labelling requirements for veterinary medicines.

Subsection (1)(l) allows for provision to be made about veterinary medicines advertising. For example, we could include a definition of advertising within the Veterinary Medicines Regulations 2013. This could provide clarity to industry, make it easier for companies to comply with requirements and provide a legal definition for enforcement purposes. We could also use this subsection to amend or supplement restrictions to advertising—for example, to ensure that animal owners are protected from misleading information and prescribers are able to make prescribing and supply decisions without undue influence from the pharmaceutical industry.

Subsection (1)(m) allows for provision to be made about animal test certificates granted under the Veterinary Medicines Regulations 2013 for research purposes. An animal test certificate is required to carry out a field trial of a veterinary medicine. Such trials are used to evaluate the safety and/or efficacy of a veterinary medicine under conditions of field use and would usually be conducted on client-owned animals.

This subsection could be used to make provision to simplify the application process for a certificate, or to allow us to introduce reduced data requirements for applications for animal test certificates for exotic or minor species. Companies must provide data to support the safety of the test product after administering it to the target species. Simplified data requirements for minor species would provide a clearer set of requirements for the industry and ensure that our systems compare favourably to those of other countries without compromising animal safety.

Question put and agreed to.

Clause 9 accordingly ordered to stand part of the Bill.

Clause 10

FEES, OFFENCES, POWERS OF INSPECTORS, COSTS

Alex Norris: I beg to move amendment 14, in clause 10, page 6, line 35, at end insert—

'(1A) The Secretary of State must publish a fees regime within three months of the date on which this Act receives Royal Assent."

This amendment requires the Secretary of State to publish their proposed list of fees in respect of veterinary medicines.

This amendment is substantially the same as amendment 11, but it relates to veterinary medicines rather than to human medicines. So, assuming that the answer will be pretty much the same as for amendment 11, I do not really want to labour the point.

Jo Churchill: The short answer is probably yes, but I will just give the hon. Gentleman half a page of explanation.

I recognise that, as before with amendment 10, amendment 11 would ensure transparency, in essence, on fees that stakeholders may have to pay with regard to veterinary medicines, such as fees for marketing, manufacturing and distribution. The fees relating to veterinary medicines are set out in schedule 7 to the Veterinary Medicines Regulations 2013, and the power in the Bill is to amend the fees where necessary, rather than to create anything new. Indeed, it is unlikely that any new or amended fees would be introduced within three months following Royal Assent. The fees are already published online and are publicly available on the gov.uk website, as I mentioned earlier.

Therefore, the amendment would create an obligation for the Secretary of State simply to republish the existing fee regime, which is already publicly available; hence the continuity element. Any proposal to amend fees or to introduce new fees would be subject to consultation. In addition, potential impacts on businesses or organisations based in the UK would be evaluated through an impact assessment, which would also be made publicly available during the consultation process.

In light of that explanation, I cordially ask the hon. Gentleman to withdraw his amendment.

Alex Norris: I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

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

Jo Churchill: Clause 10 provides that regulations made under clause 8(1) may make provision about charging fees, criminal offences and powers of inspectors. It enables the recovery of costs incurred in the administration of improvement or seizure notices under the Veterinary Medicines Regulations 2013.

We need to ensure that the regulator—the Veterinary Medicines Directorate, which I will now call VMD for ease—can continue to effectively regulate and confirm compliance with new or updated elements of the 2013 regulations. Therefore, it may be necessary to make appropriate changes to fees, offences and inspectors' powers before making any such change; as I have constantly said, consultation will take place if that is the case.

The VMD is required to recover the costs of the regulatory services that it provides from fees and charges. It is important that existing fees can be amended or that fees can be introduced to meet the cost of functions exercised by the VMD. An essential part of protecting animal, human and environmental safety is ensuring compliance with the Veterinary Medicines Regulations 2013. The existing regime imposes criminal sanctions for breaches of the regulatory framework. This clause would allow for making the breach of requirements or prohibitions introduced under clause 8(1) a criminal offence, punishable by imprisonment of up to two years.

VMD inspectors play a critical role in ensuring compliance with the 2013 regulations, helping to ensure that medicines are safe and effective for animals by monitoring their manufacture and supply. Inspectors already have powers to enter premises at a reasonable time to ensure compliance with the 2013 regulations. Clause 10 would allow for the extension of existing powers of entry and inspection to new prohibitions and requirements introduced by regulations made under the Bill.

Subsection (2) provides that regulations made under clause 8(1) may not confer a power of entry to premises used wholly or mainly as a private dwelling, unless those premises or any part of them are approved, registered or authorised for the sale of veterinary medicines under the 2013 regulations.

I commend clause 10 to the Committee.

Question put and agreed to.

Clause 10 accordingly ordered to stand part of the Bill.

Clause 11 ordered to stand part of the Bill.

Clause 12

POWER TO MAKE REGULATIONS ABOUT MEDICAL DEVICES

Alex Norris: I beg to move amendment 15, in clause 12, page 7, line 27, at end insert—

"(d) the environmental sustainability of medical devices."

This amendment obliges the Secretary of State to pay regard to the environmental impact of medical devices.

This is the "climate in all policies" amendment. We are in the middle of a global pandemic—an extraordinary time that we will all remember for the rest of our lives—but we are also in the middle of a climate emergency. Obviously, that was uppermost in all our thoughts a few months ago, and it must not fall down the order of priorities, because a similar existential threat exists as existed six months ago and it behoves us to act on it.

Amendment 15 is the first one relating to medical devices. To the principle that applies throughout the Bill of safety, availability and attractiveness, I think it would be suitable to add environmental sustainability, given that the types of materials used to create these devices could be finite resources. There could be opportunities for things to be reusable where they might at the moment be single use. I thought it important to probe this to see what the Government are doing, and could be doing, to ensure a medical devices market that promotes sustainability where that is responsible.

After tabling the amendment, I had a couple of emails from people making very fair points about things that could not be reusable. Of course, that applies to

[Alex Norris]

very many things in medicine; it is a very basic principle. I am very mindful of that. It is why the explanatory statement says "pay regard". However, I think that the two things are compatible. There will be contexts where things that are currently single use do not have to be single use. I think that we should be seeking to promote that. There will be contexts where the market and the industry should be under pressure not to use finite resources, but to use all the considerable innovation to find other solutions. I feel that if Governments do not drive that in shaping the market, nobody else will. There should be pressure for, or at least interest in, buying British, for a variety of reasons. As well as being good for jobs and our local economies, that would be very good for reducing travel miles and therefore for sustainability. We have to decarbonise every industry we possibly can, so that applies to this industry also.

This is a basic principle that I seek in every policy—even though it might be a bit boring to hear me go on about it. We have to say, "But what about the climate? What about climate change?". I think that this is the point in the Bill at which to do that. I would be interested to hear the Minister's views on it, but also to hear what the vision is for shaping this market so that it is as sustainable as it can be.

Matt Western (Warwick and Leamington) (Lab): My hon. Friend makes a very important point about sustainability, and of course linked to that is durability—the durability of the materials used in devices, particularly if a device is actually put into the human body. Of course, the durability is down to not just the effectiveness of the device or implant, but the cost to the health service of any subsequent revisions that may be needed, and so on. That is a significant cost, and therefore my hon. Friend is making an important point.

4.15 pm

Alex Norris: I thank my hon. Friend for that intervention. It is important to seek quality and build to last, and to be sure that the products that enter the market are the best possible products in the round—not just those that have the best price on the box. There are other considerations of which we have to be mindful, whether they be patient safety, the long-term experiences that my hon. Friend has referenced or environmental sustainability.

Jo Churchill: I do not think anybody in the room is unmindful of the issues of environmental impact and durability, but the hon. Gentleman's point is well made. He alluded to Baroness Cumberlege's report, which will be out on 8 July. One of the challenges is that when something is implanted in the body, it is often there for a long period of time, and we would not want it to not be durable. That is always a consideration because, for example, we would not want something biodegradable sitting in a moist, wet environment—that product is not going to be doing its job in the long term.

I will address amendment 15, which relates to the requirement on the Secretary of State to have regard to certain factors when making regulations for medical devices. Clause 12(2) sets out those factors as

"(a) the safety of medical devices;

(b) the availability of medical devices;

(c) the attractiveness of the United Kingdom as a place in which to develop or supply medical devices."

As I understand it, amendment 15 would oblige the Secretary of State to have regard to

"the environmental sustainability of medical devices"

as part of the assurances contained in clause 12(2).

I assure all hon. Members that the Government are fully cognisant of the need to ensure the ongoing sustainability of the environment, and have made major commitments not only on the broader issue of climate change, but to make sure that we are mindful of the reusability or sustainability of the things we use. All of this has to bring us back to the points that were made this morning about the need to be mindful of patient safety and so on. My understanding is that the intent of the amendment relates to the safe and environmentally friendly production of devices, which could include the transportation and sale of those devices, their import, and—where achievable—the reuse of devices after reprocessing. The hon. Member for Nottingham North has mentioned people getting in contact with him to say, "You're not having my hip after I've used it," but there are cases in which reuse would be appropriate, and we should be mindful of those.

The Bill is designed to support the safety of patients by maintaining a robust framework for the regulation of medicines and medical devices. The medical device regulations that clause 12 seeks to enable focus principally on the standards of pre-market and post-market assessment, as well as the vigilance required when placing devices on the UK market, so that UK patients feel safe about the products they can access. Amendment 15 would require consideration of facts beyond the regulator's purview and introduce an added burden on the development of regulations, particularly when changes might be needed expediently to address issues of patient safety.

I totally understand the hon. Gentleman's intention to put these issues at the forefront of our minds. However, I say gently that legislation to protect the environment, such as the Environmental Permitting (England and Wales) Regulations 2016, already exists and runs throughout the statute book, so checks and balances are in place. It is appropriate that manufacturers, suppliers and users of medical devices continue to have regard to the legislation specific to their circumstances, including the appropriate existing regulations that achieve the hon. Gentleman's aim. I therefore ask him to withdraw the amendment. If the Opposition have points to press—with specific items, for example—they should write to me directly.

Alex Norris: I feel that I have made my point. I also discussed veterinary medicine and, with a Whip in the room, it might be misinterpreted that I am making a bid to be a shadow DEFRA Minister—I would not want that to be the sense that the Committee got. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

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

Jo Churchill: Clause 12 provides the power to make changes to the Medical Device Regulations 2002, which regulate medical devices in the UK. Those regulations provide for the assessment of requirements and standards that must be met to place medical devices on the UK market, including in relation to packaging, labelling

and user instructions, and for the requirements on manufacturers to conduct post-market surveillance of devices.

The first subsection of the clause is a delegated power allowing the Secretary of State to make amending or supplementing provisions to the Medical Devices Regulations. The exercise of that power is limited to making provisions about matters specified in clauses 13 to 15. Those clauses provide an explicit and exhaustive list of topics and give more detail on how the regulation-making power may be exercised. The Committee will, I am sure, hear in-depth explanations of those clauses during our consideration of them.

Subsection (2) explains that the Secretary of State must have regard to three factors when making provisions under subsection (1): the safety of medical devices; the availability of medical devices; and the attractiveness of the UK as a place in which to develop or supply medical devices. Those three factors must be taken into account, and they have been included to provide reassurance that future provisions are made with the best intentions for the safety of people and patients in the UK, as well as the continued development of our life sciences sector.

Matt Western: I thank the Minister for giving way; she is being very generous. I want to press her on that point. She talks about reassurance, safety and how important this sector is to our economy and our scientific status. When we talk about safety, we think about gauze and metal implants and so on, and the Minister mentioned how important it is for consumer protection and assurance. However, in the way that we have a building regs centre, or whatever it is called, at Watford—it came to light after the Grenfell disaster—where building materials are tested, is there such a body that does testing of these medical materials and products in the UK? If not, is one envisaged?

Jo Churchill: I will not bluff but, off the top of my head, I think that the MHRA would look at medical devices, as it does medicines—I was looking to where my box of officials would normally be. I am fairly sure that the MHRA pays regard to devices, as with the centre at Watford to which the hon. Gentleman alluded. That centre used to do its practices at the Cardington air hangars many years ago, I think, on fire in buildings, for example. Yes, I believe that there is sufficient regulatory oversight to ensure the safety of medical devices.

Medical devices are a reserved matter in relation to Wales, Scotland and Northern Ireland. As a result, unlike the enabling powers at clauses 1(1) and 8(1), regulations made under clause 12(1) can only be made by the Secretary of State.

Question put and agreed to.

Clause 12 accordingly ordered to stand part of the Bill.

Clause 13

Manufacture, marketing and supply

Alex Norris: I beg to move amendment 16, in clause 13, page 8, line 22, at end insert—

"(1A) In making regulations under section 12(1), the Secretary of State must evaluate the extent to which the market is meeting medical need."

This amendment requires the Secretary of State to ensure that the market in devices is keeping pace with the UK's medical needs.

This is the very nub of the Bill, and of the process of leaving the European Union and transitioning away from the relationship with it. That bears some important consideration, because presumably one does not leave unless one intends to do something differently; otherwise it would not be worth it. What is not clear is whether we intend to do something differently across all pieces, or whether that just happens inevitably over time because others choose to do something within this topic area and we, by default, do not and we start to diverge.

We could make this argument for medicines, but I have restricted it to medical devices because I think it only needs to be discussed once, and it is more easily conceivable and easier for me to explain my case when we talk about medical devices. I wrenched my wrist a few weeks ago, so I went to find some wrist support. I was thinking about it in this context, because I was starting my prep for the Bill, and it is striking how I started to see things on the box that perhaps I would not previously have seen or was not looking for, about all the different codes and regulations. The schedules to the Bill have a whole litany of them, and every medical device has some configuration of them on there.

In the future that will change, or at least the Secretary of State will be able to make that change. He can make it more complicated, much easier or more onerous, depending on our perspective; but it is almost inevitable, if only by the passage of time, that it will diverge from our friends on the continent. At that point, we create a market force. We know that companies developing medical devices will now have to make a choice about how they span the two markets. Of course, these issues have had hundreds of hours of parliamentary time, so I do not intend to rehash them much further, but I think there is a legitimate anxiety about the risk—and there must be a risk—that manufacturers prioritise the EU market over us and therefore we are behind in the queue and cannot get access to meet medical need.

The purpose of amendment 16 is to be clear about that, because that will give us a chance to do something about it as a Parliament, and for the Government it will act as a call to action. The amendment asks the Secretary of State to keep the matter under constant evaluation. I am perhaps willing to take the point that any responsible Secretary of State would do so anyway, but I would like to hear that it will be uppermost in the Government's mind.

The changes we make are driven by the things we have talked about, which we see repeated for a third time under medical devices: safety, availability and attractiveness. We understand that, but because those changes could be very small, there could be a butterfly effect where we change something on a leaflet, or a badge that has to go on a box, and thus create a "Sliding Doors" moment where we start to diverge in different places. Then there will be a choice, and manufacturers will have to try to work out whether they prioritise bigger markets or smaller ones, or try to do something that pleases everybody.

I would be interested to know what conversations have happened with manufacturers and what lobbying of Government they have done about the sort of regime they want, because that is the substance of this Bill. The Bill remains a blank canvas for Ministers to paint on later; we are taking a leap of faith with Ministers here, and that is why we have sought to restrict that. It is worth understanding this, because it is one of the most

[Alex Norris]

profound implications of the Bill, and I am keen to know from the Minister how it has been mitigated and, importantly, how, and how actively, it is being considered.

Jo Churchill: Once again, I understand fully the intention of the amendment: to tease out the fact that small, incremental changes might lead to a divergence further down the line. However, I gently say that the purpose is to enable, so that, come January, we are in exactly the same place.

I will also say that innovation is a two-way street. An example is our ability to publish online to help people who might find it difficult to read the small print on paper in a packet of medicines, or who might be better able to understand from pictures how a device can be enabled or can help them. There is the chance, once we are in January 2021, to make those positive movements. That may lead to the Europeans looking and thinking, "Actually that would be useful." There is no unique place for the good idea—I think that that is what I am gently trying to say. There is no place for a particular divergence, and we would not want there to be. As I said, there is consultation with stakeholders and the industry to be done on the exact points that have been alluded to.

4.30 pm

I would like to reassure hon. Members that the Government view patient safety as the cornerstone of the medical device regulation. The availability of state-of-the-art medical devices on the market is crucial to patient safety, but also to patient quality of life. That is why clause 12(2) imposes a duty on the Secretary of State to consider the three factors that we have discussed when amending the medical device regime: safety, availability and attractiveness. In considering these aspects at every point that changes are made to the medical device regulatory regime, the Government will seek to ensure that the UK medical devices landscape can safely meet the medical needs of UK patients.

The future for medical device innovation is subject to ongoing engagement with the industry, key stakeholder groups and representative groups, and it should also be noted that there are several innovation routes that have been established in the UK, including the National Institute for Clinical Excellence and other organisations working the NHS, such as Accelerated Access Collaborative, Beyond Compliance and the health science networks, and that encourage innovation in the UK medical device industry so that both current and future clinical and patient need can be met.

As I have noted, clause 12(2) already seeks to ensure that the safety of medical devices, their availability and the attractiveness of the UK as a place to supply and develop them are at the forefront of medical device regulation in the UK. On that basis, I ask the hon. Member for Nottingham North to withdraw the amendment.

Alex Norris: I am happy to leave this matter for now; we might come back to it on Report or Third Reading.

I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Alex Norris: I beg to move amendment 17, in clause 13, page 8, line 22, at end insert—

"(k) enabling the Secretary of State to compile a register of representatives for non-UK manufacturers."

Manufacturers of medical devices based outside the UK must designate a UK representative. This gives the Secretary of State the power to compile a list of them.

This is a brief and probing amendment based on something I picked up on the road, as it were, while talking to people in the sector about what they wanted to see from the Bill and the areas that we ought to go at. I have not been able to quite stand it up in the way that I would have liked, but I am sure the Minister will humour me, in the spirit of an open constructive dialogue.

At the moment, a medical device manufacturer that is not based in the UK has to have a UK representative—and it makes absolute sense that there should be someone who is accountable for the manufacturer's actions and the impact of its products. However, the suggestion is that there may be inconsistencies as to who that person is, whether they are a genuine person of corporate interest in the company who is in a position to make or shape decisions or whether they were an appointee almost like a paper candidate. I picked that up in a couple of places, but it is anecdotal rather than something I could stand up, despite having done quite a bit of digging. I would be keen to know whether the Minister recognises that characterisation, or at least that risk.

I have not pushed the point too far in the amendment. All I am asking is that the Secretary of State would be able to make a register for the purposes of transparency. One of the suggestions was that an individual might be acting as a representative for multiple manufacturers, and that a register would help tease that out and give us a bit of transparency. I appreciate that there may be commercial sensitivities or personal identity issues, but I am sure that such issues could be managed in a sympathetic way. Indeed, I have not suggested any obligation that the register be public.

I am interested in the concept. Do we think it is a risk, and as we move into this brave new world, is this a chance to try to close that loop? Perhaps there is a better way to do it. I am interested in the Minister's views on that.

Jo Churchill: I am grateful to the hon. Member for mentioning the importance of establishing a UK device register that records UK representatives for non-UK manufacturers. We have actually spoken more broadly, but we both appreciate—as does the hon. Member for Central Ayrshire—that it is something on which we will probably need to have broader discussions in order to go forward.

First, I will look at the spirit of the amendment. I recognise that there is a desire to strengthen the Secretary of State's ability to conduct market surveillance by including in the Bill a power to compile a register of representatives for non-UK manufacturers. I wish to reassure hon. Members that the regulation-making powers in the Bill are sufficiently robust to enable the Secretary of State to conduct effective market surveillance. In particular, clause 13(1)(h) empowers the Secretary of State to make provision for the creation of a device register. Discussing how that is to be done is the next step. As hon. Members can see, the intention is already laid out.

The register would hold information about the medical devices that become available for sale on the UK market. That could include information on non-UK manufacturers, if they have devices that are sold within the UK on the UK market. Government policy is to record the responsible person for all devices available on the UK market after the transition period. Furthermore, current registration requirements allow the Secretary of State to record manufacturer information for the lowest-risk devices, custom-made devices and all in vitro diagnostic devices in the UK. Mandatory registration with the MHRA provides a level of additional scrutiny on such products that would otherwise be absent.

The Bill provides a power to expand current registration requirements to deliver a more comprehensive record of information about a wider range of medical devices entering the UK market, in order to support the role of the MHRA and its post-market vigilance activity. The will is there but, as the hon. Member for Nottingham North knows, I am very keen that we get such a register, registry or data collection, over which there is already quite a lot of confusion out there. We need to work hard with clinicians and others to ensure we get this right. On that basis, I ask the hon. Member for Nottingham North to withdraw the amendment.

Alex Norris: I really appreciate that answer, and I appreciate the Minister's commitments outside the Chamber—her work with me and the hon. Member for Central Ayrshire, whom we are all missing and who would have contributed considerably to our proceedings but cannot, for a very good reason. There is room in the space of registration. That is obviously one narrow aspect of it, so I am happy to withdraw the amendment in order to pursue the greater prize. There are subsequent amendments in my name that also look at this issue. As the Minister says, it is very complicated and there are myriad different aspects. It is potentially a barrier. It needs to be done well; otherwise, it would be a barrier to trade, which would be bad. The opportunity to come together and to hear from clinicians—to do this once and do it right—is a big prize, and I will certainly be keen to provide support in any way I can. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

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

Jo Churchill: Clause 13(1), which is similar to clause 2(1) on human medicines, provides for amending supplementary provisions to be made to the medical devices regulatory framework. Clause 13 lists the matters relating to the manufacture, marketing and supply of medical devices that may be under clause 12(1). The list is exhaustive in order to provide clarity.

Paragraphs (a) to (d) of subsection (1) provide the changes that can be made to regulatory requirements, which must be met before a product can be placed on the UK market, and outlines who can make such an assessment. The provision includes requirements about the characteristics of devices, such as design, manufacture and packaging, and the requirements placed on people involved in the marketing and supply of devices. Those paragraphs also allow for changes to be made to the rules governing the appointment of a specified person or persons, UK-based or not, to assess and certify that medical devices meet all relevant requirements. Changes may be made to conformity assessments, which are assessments of whether requirements, which could include conforming to agreed standards, have all been met. Under subsection (1)(e) and (f) provision could be made about the information to be provided to demonstrate that a device has met regulatory requirements. That could include specifying declarations that manufacturers must make, or certificates that must be provided, to show that a device has been through the appropriate kind of conformity assessment.

Clause 13(1)(g) enables provision to be about labelling, packaging, and information requirements for devices. That might, for example, include specifying warnings or expiry dates that must be included on the label or packaging for a device, and what information to include in the instructions for the use of the device.

We have considered additional ways in which we can improve our regulatory system to improve patient safety and aid market surveillance activities undertaken by the Medicines and Healthcare Products Regulatory Agency. One is the provision made in clause 13(1)(h), which would empower the Secretary of State to make registration requirements for devices marketed in the UK about the registration of devices and their manufacturers and suppliers, including information—this is probably our starting point—to be entered in a register. That is where I do not want the landscape to get confused. It is important that the register sits as that important piece.

Regulations made under clause 12(1) and relying on clause 13(1)(h) will enable the MHRA to create a register of medical devices available on the UK market. That could be requirements to increase the scope of current registration rules. Currently the lowest risk class of device—where they have been self-assessed by the manufacturer rather than assessed by a notified body—is required to be registered with the MHRA. Specified information in such a register, which would not include commercially sensitive information or personal data, could be made publicly available under clause 13(1)(h)(iii), allowing clinicians and patients access to information on the device that they intend to use. Again, there would be transparency.

Under clause 13(1)(i) and (j) changes could be made to the rule around investigations and evaluations for safety, performance and clinical effectiveness, and monitoring of performance through market surveillance. Having the ability to update the rules is essential to maintaining patient safety standards.

The UK does not operate in isolation to the rest of the world, and we have provided at subsection (2) that, where regulations are made relating to matters in clause 13(1)(a)—requirements that must be met in relation to medical devices—those requirements can refer to international agreements or standards for marketing or supplying medical devices.

Question put and agreed to.

Clause 13 accordingly ordered to stand part of the Bill.

Clauses 14 to 16 ordered to stand part of the Bill.

Ordered, That further consideration be now adjourned.–*(Maggie Throup.)*

4.44 pm

Adjourned till Wednesday 10 June at twenty-five minutes past Nine o'clock.

Written evidence to be reported to the House

MMDB01 Pharmacy2U

MMDB02 Healthy.io

MMDB03 General Pharmaceutical Council

MMDB04 Federation of Manufacturing Opticians

MMDB05 Institute of Physics and Engineering in Medicine (IPEM)

MMDB06 Ethical Medicines Industry Group (EMIG)

MMDB07 Law Society of Scotland

MMDB08 Cystic Fibrosis Trust

MMDB09 British Dietetic Association, the Royal College of Occupational Therapists, the British and Irish Orthoptic Society, the Society of Radiographers, and the Royal College of Speech and Language Therapists

MMDB10 Cancer Research UK

MMDB11 Advanced Accelerator Applications (AAA)

MMDB12 Independent Fetal Anti-Convulsant Trust (INFACT)

MMDB13 Muireann Quigley, Professor of Law, Medicine and Technology; Jean McHale, Professor of Healthcare Law; Dr Rachael Dickson, Research Fellow; and Dr Laura Downey, Research Assistant, University of Birmingham

MMDB14 NOAH (National Office of Animal Health)

PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT
GENERAL COMMITTEES

Public Bill Committee

MEDICINES AND MEDICAL DEVICES BILL

Third Sitting

Wednesday 10 June 2020

CONTENTS

No proofs can be supplied. Corrections that Members suggest for the final version of the report should be clearly marked in a copy of the report—not telephoned—and must be received in the Editor's Room, House of Commons,

not later than

Sunday 14 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)

Yohanna Sallberg, *Committee Clerk*

† attended the Committee

Public Bill Committee

Wednesday 10 June 2020

[Philip Davies *in the Chair*]

Medicines and Medical Devices Bill

9.25 am

The Chair: Before we resume, I remind hon. Members of the preliminary points that I made on Monday. Members will understand the need to respect social distancing guidance. I remind them to switch electronic devices to silent mode and that tea and coffee are not allowed during sittings.

The selection list for today's sitting is available in the room. That shows how the selected amendments have been grouped for debate. Grouped amendments are generally on the same or a similar issue. Please be reminded that decisions on amendments take place not in the order in which they are debated, but in the order in which 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. Again, the *Hansard* Reporters will be most grateful if Members could email any electronic copies of their speaking notes to hansardnotes@parliament.uk.

Clause 17

Suspension notices

Alex Norris (Nottingham North) (Lab/Co-op): I beg to move amendment 29, in clause 17, page 10, line 12, at end insert—

"(f) advertising it."

This amendment allows the enforcement authority to prevent an individual who has been served a suspension note from advertising their product.

It is a pleasure to be back. Monday's discussions were of a high quality and in a good spirit, which is what we need at this time, so I am glad to be here and back at it.

This is a short amendment: again, I want to talk about the issue rather than do anything else. Clause 17 sets the context and is mirrored in clause 18, to which I have tabled amendment 18. It sets out what the Secretary of State or the enforcement authority can do in relation to a faulty product, a medical device that is presumably dangerous or certainly not known to be safe. It includes a list of five things that can be prohibited under either a suspension notice or a safety notice. This prevents an individual from

"(a) supplying the medical device;

(b) offering to supply it;

(c) agreeing to supply it;

(d) exposing it for supply;

(e) possessing it for supply."

I would add a sixth one—advertising it for supply. I flagged this up with the Minister the other day and will obviously be interested to hear her reply. I am conscious that she has the collective might of the legal brains of the whole Government. It could be that I have spotted a gap, or that I have not. That depends on whether advertising is covered by "offering to supply it" or "exposing it for supply".

I want to talk about a particular phenomenon—the current way in which clickbait is used. For example, over the weekend, I saw an article that normally would be up my street. It said, "Jason Statham says he no longer needs to do the 'Fast and Furious' films". I am a big fan of the "Fast and Furious" franchise, and that would grieve me enormously. I did not click on the article, because it was obviously nonsense, but I later saw an article about the very same thing. It mentioned Jason Statham and other people, and when you click on that type of thing, it takes you through to bitcoin. It basically said that he does not need to do films anymore, because he has made so much money on bitcoin and so can you. There is an argument to be had about cryptocurrencies, but the issue there is people being shown one thing that actually leads them to something else.

In the medical devices space, it is very easy to see equivalent things for people to click on. They will show someone with dramatic weight loss and then say, "You won't believe how they did it." In this case, there will be a picture of a medical device, and the idea is that someone says, "Wow! I've found a magical device. I can do the same. I can do it just like this celebrity." Then they click through and it takes them to diet pills. I would argue that at no point there—there is no price; the article may not name or price the product, but just picture the product—have those responsible exposed it for supply, because it would be possible to argue that we literally cannot buy it, it is just a picture and certainly it has not been offered for supply.

Again, I am happy to take the lawyers' guidance on this, and I hope that the Minister will help us with that. I just want to ascertain whether that gap—the thing that would legitimise a product, the demonstrating of it for another end—is one that we have to close.

The Parliamentary Under-Secretary of State for Health and Social Care (Jo Churchill): I would also like to say what a pleasure it is to resume under your chairmanship, Mr Davies.

Amendment 29 seeks to amend clause 17 with regard to the suspension notices. I understand totally why hon. Members are looking to double-check where we are. The clause provides an enforcement authority with the power to serve a suspension notice on a person, where doing so is considered necessary to restrict the availability of a medical device in order to protect health and safety. It lists a number of prohibitions that may be imposed, and seeks to add a specific prohibition on advertising a medical device.

The Government recognise that the intention behind the amendment is to equip the enforcement agency with the ability to prohibit a recipient of a suspension notice from advertising a medical device where there is a need to protect health and safety. I assure hon. Members that the enforcement authority has the ability to do what the hon. Member for Nottingham North is asking and prohibit the advertising of a product already catered for in the clause. That is already in the Bill as it is currently drafted.

Hon. Members will note that prohibitions that may be impose include, in clause 17(2)(b), "offering to supply", which encompasses advertising or an advertisement. Although I am grateful for the probe, I respectfully ask the hon. Gentleman to withdraw the amendment.

Alex Norris: I am content with that. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 17 ordered to stand part of the Bill.

Clause 18

SAFETY NOTICES

Alex Norris: I beg to move amendment 18, in clause 18, page 10, line 34, at end insert—

"(f) advertising it."

This amendment allows the enforcement authority to prevent an individual who has been served a safety note from advertising their product.

Alex Norris: This is exactly the point that I just made, so I will not labour it.

Jo Churchill: My explanation covered both points. Clause 18 provides an enforcement authority with the power to serve a safety notice on a person where doing so is considered necessary to restrict the availability of a medical device in order to protect health and safety. It provides the enforcement authority with discretion about the prohibitions that may be imposed. The amendment seeks to add a specific prohibition on advertising a medical device. We recognise that the purpose behind it is to equip the enforcement agency. I would like to reassure hon. Members that that sits in the Bill. On that basis, I commend the clause to the Committee.

Alex Norris: I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 18 ordered to stand part of the Bill.

Clauses 19 to 23 ordered to stand part of the Bill.

Clause 24

DEFENCE OF DUE DILIGENCE

Jo Churchill: I beg to move amendment 2, in clause 24, page 13, line 26, leave out 'case' and insert

'proceedings for such an offence'.

This amendment, and amendments 3, 4, 5, 6 and 7, amend certain provisions to ensure they operate effectively in relation to Scotland.

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

Government amendments 3 and 4.

Clause stand part.

Government amendments 5 to 7.

Jo Churchill: Amendments 2 to 7 relate to the clauses about defences available for offences under clause 23 and regulation 60A to be inserted into the Medical Devices Regulations 2002 by schedule 2.

Clause 23 will provide that it is an offence to fail to comply with a compliance, suspension, safety or information notice. Schedule 2 makes it an offence to fail to comply with certain provisions of the Medical Devices Regulations 2002. Further, the Bill provides that a defence of due diligence will be available with respect to each of those offences. That means that a person charged with an offence under either clause 23 or regulation 60A will be able to argue that they have not committed an offence because they took reasonable steps to avoid doing so.

The provisions that make those defences available are in clause 24 and schedule 2. It is those provisions that we seek to amend. Amendments 2 to 4 are to clause 24 and amendments 5 to 7 are to schedule 2.

Alex Norris: I do not have an awful lot to say. I am comfortable with the amendments, and I know that the hon. Member for Central Ayrshire is, too, as she put her name to them. I always find it reassuring when there are Government amendments during Committee, as it means they are still reading the Bill, which is a good thing. So, yes, we are content.

Jo Churchill: On that basis I commend the amendment to the Committee.

Amendment 2 agreed to.

Amendments made: 3, in clause 24, page 13, line 32, after 'hearing' insert 'of the proceedings'.

See the explanatory statement for Amendment 2.

Amendment 4, in clause 24, page 14, line 2, at the end insert ', and

(b) the reference in subsection (3) to "the hearing of the proceedings" is to be read as a reference to "the trial diet".'—*(Jo Churchill.)*

See the explanatory statement for Amendment 2.

Clause 24 , as amended, ordered to stand part of the Bill.

Clauses 25 and 26 ordered to stand part of the Bill.

Schedule 1

MEDICAL DEVICES: CIVIL SANCTIONS

Alex Norris: I beg to move amendment 20, in schedule 1, page 31, line 16, after 'guidance' insert

'within three months of this Act receiving Royal Assent'.

This amendment requires the relevant guidance relating to enforcement to be published within 3 months rather than at an undetermined time.

The schedule compels the Secretary of State to provide guidance on sanctioning powers and how they are likely to be used. Those are the new civil powers—among the bigger changes in the Bill—and the guidance will cover when they are likely to be used, the likely level of fines, and the cost recovery, which we spoke about earlier. They are clearly an area of significant interest. Those civil powers are new and important, and we will cover them a bit when we debate the next amendment. At the moment, schedule 1 states that:

"The Secretary of State must prepare and publish guidance".

That is it. The amendment seeks for that to be done within three months. Three months might not be the right period of time, but I am keen to test when we are likely to see the guidance and whether we should put a bit of structure around that.

Jo Churchill: I would like first to address the intention behind the amendment. I recognise that it is driven by the desire to ensure that the Government issue guidance on the new civil sanctions regime within three months of the Bill gaining Royal Assent. The new civil sanctions regime will complement the consolidation of the current enforcement regime, enabling the Medicines and Healthcare products Regulatory Agency to impose a monetary penalty, an enforcement cost and a recovery notice, or to accept an enforcement undertaking as an alternative to criminal prosecutions. That will enhance the MHRA's ability to incentivise compliance with the Medical Devices Regulations 2002.

Under paragraph 13 of schedule 1, the Secretary of State has to publish guidance on the new civil sanctions regime. However, the timeframe for doing so is not specified on the face of the Bill. Before it is fully operational, the new civil sanctions regime provided for by the Bill will require further provision, to be set out in supplementary regulations made under paragraph 9 of schedule 1. The regulations will cover matters such as enforcement and monitoring of compliance with enforcement undertakings and appeals.

Clause 40 provides that any regulations made under paragraph 9 of schedule 1 must be consulted on. There needs to be enough time to do that, which is why a three-month period is perhaps too truncated. The Government wish to allow sufficient time for such a consultation on these matters before we make the regulations, in order to ensure that they best fit the situation that we are trying to enforce. As I have explained, the civil sanctions regime will not be fully effective before the regulations are made. Under paragraph 13 of schedule 1, the Secretary of State must also consult before issuing guidance on the new regime.

It is right that we consider the views of stakeholders. As we discussed at length on Monday, this is about getting it right for patients and all stakeholders before we bring the regulations into force. It is important that we allow sufficient time to engage effectively and to ensure that we act in the best interests of both patients and the healthcare sector. The effect of the amendment would be that the Government are required to consult on, and publish guidance on, the civil sanctions within a tight three-month period before the regulations have been made, and at a point when the consultation might still be ongoing, so that we arrive at the best place.

Paragraph 13 of schedule 1 already places a duty on the Secretary of State to publish the guidance in order to be transparent, and the new civil sanctions regime will require consultation and secondary legislation. It is therefore impractical to specify on the face of the Bill that we would have a timeframe for doing so. On that basis, I hope that the hon. Member understands that we wish to get this right, and that he will withdraw the amendment.

Alex Norris: I am happy with that, certainly for the purpose of greater consultation, because a theme in the written evidence is that the sector wants to continue to talk about such things and get them right. We will return to this issue when we debate the next amendment.

I hope the Government will not leave it too long. There is a very important bit of guidance that the Secretary of State is compelled to publish under the Modern Slavery Act 2015, but we have still not seen it. The regulations are likely to be less challenging than that. I do not like the open-ended space, so I hope the Government will move on precipitously. On the basis of the Minister's answer, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Alex Norris: I beg to move amendment 21, in schedule 1, page 32, line 18, leave out "from time to time" and insert "every 12 months".

This amendment requires the Secretary of State to report back on their use of civil sanctions every year rather than at an undetermined frequency

Again, this helps us to delve into the new sanctions regime and to talk about the Medicines and Healthcare products Regulatory Agency. As we see from the written evidence, there is a lot of interest in that. The Bill seems to do two things, certainly regarding the Medicines and Healthcare Products Regulatory Agency: consolidate disparate bits of legislation that govern its activity, and provide it with new civil powers.

9.45 am

On the former, it is clear from the explanatory notes to the Bill that, in the Government's opinion, the current structure of legislative powers hinders the MHRA. As an Opposition Front Bencher, I share their view and support the principle. The latter point, about the new civil powers, came up frequently in conversations with patient safety campaigners, and I know that the Independent Fetal Anti Convulsant Trust mentioned it in its written evidence. Generally, the Opposition are reticent about the Government relying on civil rather than criminal powers, especially when it comes to things that can cause significant and serious harm to individuals.

We know about the issues covered by the Cumberlege review and the incredible potential for life-altering harm through negligence, malpractice or similar. I would not want to see a situation where the ease of prosecution meant that we downgraded those things to a massive fine on a massive company, because they can eat those—it is almost priced in—and carry on regardless. That would not feel like justice, so I am keen to hear from the Minister that that is not the case and that the Government do not think that it would be the right thing to do.

However, on the broader point about the civil powers, I think this is the right thing to be doing. Paragraph 96 on page 19 of the impact assessment says:

> "MHRA prosecutions for non-compliance are rare but do occur. Since 2008, the MHRA has brought 3 prosecutions, 2 of which ended in convictions, and one ended in acquittal."

That is only three in more than a decade. We need to balance that against the fact that, in 2017-18 alone, the MHRA seized 9.5 million falsified medical products. Not all of them would be covered by what it could do through prosecutions on medical devices, but that shows the balance of risk and how hard those pursuing nefarious ends will push these things.

Frankly, if I had got that information about three prosecutions in over a decade via a written question rather than an impact assessment, I would be pushing the Minister on what she was going to do differently in the future. Therefore, I do not think I can start sniping when an alternative regime is proposed, and I will not

do so, but there is a risk that we could downgrade exceptionally serious breaches of patient safety, and I hope we will not.

Come what may, whatever the intentions, this is a bit of a leap into the dark in terms of whether these provisions will work. In amendment 21, we therefore ask the Secretary of State to report every 12 months so that they can be monitored. I think the Government accept the basic principle, because they have put a similar burden on the Secretary of State, but only to report from "time to time". I did not like that phrase, or really know what it meant, so perhaps, in a spirit of co-operation, the Bill could be tidied up, either today or at a later date. I would certainly be keen to press the point in the remaining stages of the Bill.

The amendment would also allow us to establish two further things. First, page 19 of the impact assessment states that these civil powers will operate at the burden-of-proof level of a criminal charge, rather than the traditional civil balance-of-probabilities level. That is interesting, and it sent me off for hours and hours, looking through all sorts of civil orders. Criminal behaviour orders—what we might have called antisocial behaviour orders in the past—have that criminal burden-of-proof level. Current domestic violence prevention orders work on a balance of probabilities. That sent me to the new Domestic Abuse Bill, in which the new domestic abuse prevention orders also work on a balance of probabilities, or on the civil, rather than the criminal, level. Can the Minister give us clarity about how the Government chose to set the burden of proof at a criminal level? This is important and will no doubt restrict the use of such civil orders. An annual review would allow us to see whether it has been hindered unnecessarily or undesirably.

Secondly, an annual report allows us to evaluate the MHRA itself. Let me start by saying that the MHRA has a really challenging job. It is our major line of defence in protecting the public from potentially catastrophic harm. It is regulating a massive industry with exceptionally powerful stakeholders on all sides. Given the extra powers, I am keen to know what extra capacity it will have in order to use them effectively.

I mentioned this on Monday, and to an extent I am laying breadcrumbs for remaining stages of the Bill, but we will see Baroness Cumberlege's report on 8 July, by which time we will probably not have gone through the remaining stages. The report could have profound implications for the structure and operation of the MHRA; it is going to tell us about significant harm, what happened and perhaps how it could have been prevented.

It is unthinkable that the regulator would not be part of that conversation, so the Minister may have to return to make significant changes before the Bill passes. Even if not, we will need to know that our regulator can cope and is sufficiently resourced, and that it is independent enough and effectively operating the new powers. An annual report would do that. I know that the Government are committed to the principle of a report, and I wonder whether "annually" might be better than "from time to time".

Jo Churchill: Once again, I recognise that the hon. Gentleman is probing, to ensure we make good legislation. For that, I am extremely grateful.

The Government have every intention of providing greater transparency about the safety and effectiveness of medical devices on the UK market, including on how our use of civil sanctions will achieve that aim. On that basis, I confirm that the Cumberlege report will definitely be with us on 8 July, which I do not think I stated during proceedings on Monday. I take on board the hon. Gentleman's point that we may well be looking at things in the round.

Civil sanctions will provide an alternative to criminal prosecution where the latter is not suitable. If, for example, a breach is judged to have had the potential to cause harm but it does not, the civil sanction is a second tool in the toolbox. As the hon. Gentleman said, there have been very few prosecutions in the last decade. Criminal prosecutions can be used where the breach of regulations leads to a serious incident or death, or where a manufacturer has directly contravened the conditions set out in a safety or suspension notice. As I am sure he will agree, other incidents very often need a flag raising, and that is the point of bringing civil sanctions into the legislation.

Currently, as the hon. Gentleman said, the Secretary of State is committed, under paragraph 15 of schedule 1, to publishing reports on the use of civil sanctions from time to time. The requirement to publish reports on the use of civil sanctions is in line with existing obligations on other Government agencies that already operate a civil sanctions regime for their sector. The Environment Agency is one—in respect of environmental civil sanctions—while the Secretary of State for Business, Energy and Industrial Strategy, who is responsible for enforcing the Ecodesign for Energy-Related Products Regulations 2010, is another. Those regulations explicitly state that reports on the use of civil sanctions will be published "from time to time".

The new civil sanction regime would require supplementary legislation, as per paragraph 9 of schedule 1. A consultation on the supplementary legislation would be necessary to ensure that the new regime is operational. I assure Members that the Government intend to publish reports on their use of those measures at regular and appropriate intervals, and the hon. Gentleman will bring me up on that. The Government may indeed decide that reporting annually is appropriate. However, as the new regime will require secondary legislation, which must be consulted on before it comes into force, it is not practical to specify at this point the frequency of Government reports on the use of civil sanctions.

On the hon. Gentleman's specific point about burden of proof and how we arrived at that, I will write to him. On that basis, I invite him to withdraw the amendment.

Alex Norris: On the principle of civil sanctions, we are content. I am really grateful to the Minister for her offer to write to me about the burden of proof, and I will definitely take her up on that. It is important to reflect on why that is different in different cases.

I meant to refer to the potential to do harm, which is something worth reflecting on that, and we can talk about it in the remaining stages. At the risk of going into pub chat—if only—let us imagine that I throw a stone at someone. Whether I hit or miss, have I committed an offence? Does it matter that I have good or poor aim? When it comes to medical devices, if we find something with the potential to do significant harm, the fact that it has not yet done so would certainly not be a

[Alex Norris]

good enough reason to downgrade the way in which that was treated. Again, we can reflect on that another time, and it is also tied up with the burden of proof, but on the basis of the answers so far, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Schedule 1 agreed to.

Clauses 27 to 29 ordered to stand part of the Bill.

Clause 30

RECALL OF MEDICAL DEVICE BY ENFORCEMENT AUTHORITY

Alex Norris: I beg to move amendment 28, in clause 30, page 16, line 23, at end insert—

"(4) The Secretary of State must, within 24 months of this Act receiving Royal Assent, lay a report before Parliament reviewing uses of this clause."

This amendment requires the Government to review any use of the recall powers made in the first 2 years of the Act.

Again, this is a simple amendment. The clause governs the recall of a medical device by the MHRA. That is of significant public interest—recall, obviously, is important to people. It is also really challenging, and we have all seen that, whether with washing machines, cars or whatever. Once devices are out there, it is hard to recall them, so we want to know that these powers are working effectively.

The obligation that the amendment would put on the Secretary of State is to provide, within two years, a report on when recall has been used. That would do two things: first, it would allow us to evaluate how effectively recall was being used; and, secondly, it would act as a further publicity tool, so that people understood that the device has been recalled and, if they were still in possession of it, that they could do something about it.

At the moment, subsection (2) states: "The authority"—the MHRA—

"may take such steps as it considers necessary to organise the return of the device",

but the clause does not quite say anywhere that the MHRA will then tell people what it has done. If that is implied, I am probably willing to accept that answer, but I am keen for the Minister to note that the Government's clear intent is not only to organise the recall of unsafe devices, but to publicise that significantly, such that it will be reasonable to expect people to see such publicity and therefore to act on it.

Jo Churchill: The Government consider the new recall power to be crucial to ensuring that unsafe devices are removed from the market. It is important to note, however, that subsection (3) requires that the power is used only as a last resort.

The Bill introduces this statutory power for the MHRA, on behalf of the Secretary of State, to conduct recalls on the rare occasions when a manufacturer is either unwilling to carry out a recall imposed under clause 18 or is unable to do so because the manufacturer no longer exists as an entity. I am sure Members will agree with this power, as it is intended to ensure the safety of devices for patients and, without it, there would be a gap. In the case of companies unwilling to take action, devices that are not recalled might well present risks to patients. It is right that the regulator can take action if and when companies fail to recall devices.

The statutory power also addresses an anomaly in the existing enforcement regime, whereby the MHRA has the statutory power to conduct a recall under the General Product Safety Regulations 2005 where the medical device in question meets the definition of a consumer good—typically, a low-risk medical device—but the MHRA does not currently have the commensurate statutory power to conduct recalls for higher-risk medical devices that are not also consumer goods under the GPSR. That would appear to be an inconsistency that does not align with risk to patients. I am sure all hon. Members would agree that, where possible, that is what good legislation should do, and the Bill seeks to correct that anomaly.

10 am

The Bill already provides the Government with the power to make public the details of recalls they conduct, because clause 34(2) allows the Secretary of State to disclose information for the purpose of warning the public—this is what I think the hon. Gentleman was alluding to—about concerns relating to the safety of a medical device. The Government consider that such information could include information about whether a medical device has been recalled. Accordingly, I reassure hon. Members that the Government intend to act transparently when they conduct recalls, using the power provided in clause 30. On that basis, I ask the hon. Gentleman to withdraw the amendment.

Alex Norris: I will not labour the point, but the Government must act not just transparently, but transparently, publicly and proactively. That is something we would be really keen on.

Matt Western (Warwick and Leamington) (Lab): On a point of clarification, at what point does the MHRA intervene? At what point is the threshold—that is perhaps a better way of putting it—at which a recall is demanded? Depending on the product, at what point is that necessary and who bears the cost? I am not sure whether that should be covered by the clause, or whether it is simply within the remit of the MHRA.

Alex Norris: That is interesting, and if the Minister wants to intervene to address that point, I will take an intervention. Otherwise, my best guess is that it would be covered by the regs and, presumably, subject to consultation. However, I hope the Government have a clear trigger point, so that we are all clear and transparent about what will happen.

Jo Churchill: The MHRA has a specific compliance department. It works on a case-by-case basis, and it would issue a notice—see clause 18—and it would move forward on that basis with an individual recall against a company. I hope that clarifies the situation.

Alex Norris: I am grateful for that clarification. On the basis of the answer I have received, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 30 ordered to stand part of the Bill.

Clauses 31 to 36 ordered to stand part of the Bill.

Schedule 2

OFFENCE OF BREACHING PROVISIONS IN THE MEDICAL DEVICES REGULATIONS 2002

Amendments made: 5, in schedule 2, page 34, line 8, leave out "case" and insert

"proceedings for such an offence".

See the explanatory statement for Amendment 2.

Amendment 6, in schedule 2, page 34, line 14, after "hearing" insert "of the proceedings".

See the explanatory statement for Amendment 2.

Amendment 7, in schedule 2, page 34, line 28, at the end insert "and

(b) the reference in paragraph (3) to 'the hearing of the proceedings' is to be read as a reference to 'the trial diet'."—*(Jo Churchill.)*

See the explanatory statement for Amendment 2.

Schedule 2, as amended, agreed to.

Clauses 37 to 42 ordered to stand part of the Bill.

Clause 43

COMMENCEMENT

Alex Norris: I beg to move amendment 19, in clause 43, page 24, line 17, leave out

"on such day or days as the Secretary of State may by regulations made by statutory instrument appoint"

and insert

"six months after this Act receives Royal Assent."

This amendment brings the enforcement regime into force at a defined period after Royal Assent rather than at a date of the Government's choosing.

Having accepted the principle of the new enforcement regime and seeing its potential, I am keen to know when it will be in place and what the Government's intentions are for getting on with it. Clause 43(3) says:

"Chapters 2 and 3 of Part 3"—

the bit that governs the enforcement and disclosure around medical devices—

"come into force on such day or days as the Secretary of State may by regulations made by statutory instrument appoint."

Basically, that means at some point in the future.

The amendment, which is in my name and the name of the hon. Member for Central Ayrshire, suggests the regime should come into force within six months of Royal Assent. As was said in our earlier discussion, I imagine that the Government want to return to consultation on that point, so that might not be the right period. We are keen to know that the Government intend to get on with it, however, because there may be some push-back from those with vested interests who do not want the scheme to go ahead. I talked about there being three prosecutions in 12 years; we are likely to see much greater activity than that, and there will be those with vested interests who do not want that to happen.

I am keen for the Government not to leave this forever. If we accept in primary legislation that the regime is going to happen and is a good idea, that is what matters, and it should happen at a defined point. I am keen to know what the Government see as the timeline for introducing it. As Parliament has decided that we will do this, I would like a firm commitment on the record that we are actually going to do it.

Jo Churchill: I am grateful to the hon. Gentleman for raising, through amendment 19, the issue of the commencement of chapters 2 and 3 of part 3 of the Bill, which is concerned with medical devices. Chapter 2 introduces a new enforcement regime that includes the civil sanctions set out in schedule 1, which we discussed. Chapter 3 concerns data and disclosure provisions, and contains a number of consequential amendments, which facilitate the introduction of the new enforcement regime in chapter 2.

On chapter 2, as I have said, a key element of the new enforcement regime is the addition of civil sanctions, which will act as a flexible, proportionate enforcement mechanism to enhance the MHRA's ability to incentivise compliance. Supplementary regulations must be made under paragraph 9 of schedule 1 before the new civil sanctions can be fully operational. Those regulations, which could relate to matters such as the enforcement of a monetary penalty regime, monitoring compliance with an enforcement undertaking, and the provision of appeals, are subject to a consultation requirement, as set out in clause 40. It is right that we consider the views of stakeholders before bringing the regulations into force, and it is important to allow for time to engage effectively, so that we can ensure that we act in the best interests of patients, and thereby in the best interests of the healthcare sector that serves them.

The data and disclosure provisions in chapter 3 will provide greater transparency about the safety and effectiveness of medical devices on the UK market. I am sure we all agree that that is what we are after: knowing what is going where and helping whom, and, if there is an issue, being able to isolate and highlight it, and then provide a remedy. The Government are exploring how we can ensure that the new powers are as effective as possible and secure the needs of the healthcare community, patients and the wider public. It is therefore appropriate that due consideration be given to how the powers can most effectively be used before they are commenced. An amendment putting in place a deadline by which the powers must come into force could limit the MHRA's ability to find the most effective route, and it could limit the time that MHRA has before commencement for the important process of engaging with stakeholders on the powers.

Finally, the consequential provisions in clause 36 are linked to the disapplication of the previous enforcement regime in part 2 of the Consumer Protection Act 1987. They too must be commenceable by regulations, so that they come into force at the same time as the new enforcement regime.

I reassure hon. Members that the Government are committed to bringing the enforcement, data and disclosure chapters of the Bill into force as soon as is appropriate, in order to enhance the safety of the medical devices regime, which I think we all see as important. I therefore ask the hon. Member for Nottingham North to withdraw the amendment.

Alex Norris: The final part of that answer answered my question. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Clause 43 ordered to stand part of the Bill.

Clauses 44 to 45 ordered to stand part of the Bill.

New Clause 6

REGISTRATION OF MEDICAL DEVICES

'(1) The Secretary of State shall by regulations establish a UK Registry of all devices implanted into patients on a long-term basis.

(2) The identifier details of any devices implanted into patients, on a long-term or permanent basis, must be registered.

(3) The information registered must include—

(a) The unique identifier of the patient into whom the device is implanted;

(b) The Clinician responsible for the procedure;

(c) The hospital or clinic in which the procedure is performed;

(d) A standardised description of the device;

(e) The unique identifier code of the device implanted.

(4) Efforts must be made for this unique identifier data to be gathered by barcode reader as in the trial of 'Scan for Safety'.

(5) This Registry shall require linkage from all currently established speciality device registries, in current operation, to avoid duplication of registration.

(6) Devices without any form of specialist registry currently available shall be registered in this UK Registry.

(7) Governance structures regarding the management and access to registry data shall be established after consultation with stakeholders including but not limited to—

(a) the appropriate authorities as defined in Section 1 (4);

(b) all UK based Royal Colleges of Surgery or Radiology and any others representing clinicians involved in such procedures;

(c) Managers of current speciality device registries;

(d) the Medicines and Healthcare products Regulatory Agency;

(e) the Directors of each of the four UK based National Health Services;

(f) healthcare quality improvement bodies from each of the four UK based National Health Services;

(g) representatives of the Healthcare device manufacturing sector;

(h) academics with expertise in the design and maintenance of registries;

(i) additional stakeholders as identified during the development and maintenance of such a registry.

(8) Patient information from such a registry shall be provided to clinicians if there is concern regarding the management of or complications from any implanted device to allow closer monitoring or removal if so warranted."

The aim of such a UK register is to ensure earlier recognition of complications from implantable devices and allow the easy identification and urgent recall of affected patients should such a concern be recognised.

Brought up, and read the First time.

Alex Norris: I beg to move, That the clause be read a Second time.

I am pleased to give this clause a run-out on behalf of the hon. Member for Central Ayrshire. We have missed her during these proceedings, and I hope that conversations are ongoing through the usual channels about how we can make Public Bill Committees work and perhaps give hon. Members who cannot be here—for very good reasons—a chance to contribute.

This is the final new clause, but it is by no means the least important. In fact, it has the most potential to be a clause with which we do something quite exciting. A great deal of pain has been caused in the past. I will not get ahead of the Cumberlege review, but when things go wrong in the space of medical devices, they go wrong catastrophically and in a life-altering fashion. None of us would want to see that; all of us would want to do anything we can to avoid or mitigate that harm.

The new clause would establish an exciting regime of registration of medical devices. It would provide information on a granular level—we have seen the level of detail that the hon. Member for Central Ayrshire has put into it—so that we know exactly what medical device has gone where and for what purpose. This is a complex area. We talked on Monday about the various different registries or registrations we could have, and all are complex and require reflection. This would be a good part of marking the Government's card. Since Monday, we have had very good informal conversations about how we can take this forward.

10.15 am

I believe there is a clear willingness on the Government's part to come up with something really good, and to work by consensus to establish it. That is a good thing. We can pull together Members with expertise from across this place and the other place, to come up with something that really works, and which brings stakeholders in, too; this is in their interests. We want something practical that works. We are exactly in the right space. I would be interested to hear the Minister's comments.

Jo Churchill: As the hon. Gentleman knows, I am also enthused and excited about the register, because it offers us a space to do something good. I am very grateful to him and the hon. Member for Central Ayrshire, to whom I spoke at the weekend, as I said on Monday, and I noted that she would not be with us for Committee proceedings.

A registry of long-term implantable medical devices as suggested in new clause 6 is of significant interest to many Members. On Second Reading, many Members put forward good ideas on how we could make a register work for the benefit of patients. We should consider this in the context of the forthcoming report from the independent medicines and medical devices safety review and the matters it looked into, particularly the use of pelvic mesh, and how we oversee medical devices, including post-market surveillance. It is not only the point when the device is implanted that is vital, but also the potential impacts some years later. I know we all recognise the critical importance of ensuring that patients are heard and that concerns about medical devices are identified and dealt with quickly and effectively. That must be at the forefront of our minds. As the hon. Gentleman said, the impact on an individual's life can be significant.

New clause 6 is similar to new clause 1, which was tabled in the name of my hon. Friend the Member for Newton Abbot (Anne Marie Morris). I know that she and many other Members in the House and the other place are interested in what more we could do to improve the tracking of implantable medical devices. The issue has also been a subject of interest to the Health Quality Improvement Partnership and the Royal College of Surgeons. It is very topical.

Clause 13(1)(h) provides for the creation of a register of medical devices to capture which devices are available on the UK market and to ensure that the MHRA can identify which device has been produced by which

manufacturer. There has been some confusion in some of the written evidence as to whether that is intended to constitute a registry. A registry as in new clause 6 suggests bringing together patient and clinical information with device information. We have device registries, such as the national joint registry in the UK, which is seen as a global exemplar, so it is important to make sure that we do what we need to in order to enhance what is already in the system.

I understand the intent behind the new clause and, as ever, I am keen to understand what more we can do to protect patients in a fast-moving and constantly innovating environment, but I am not sure that new clause 6 is practical. The hon. Member for Central Ayrshire and I discussed the fact that it was heading in the right direction, but we need to work on it.

Patient safety absolutely underpins everything in our approach to regulation of medical devices in the Bill. It is the key consideration for all of us, as set out in clause 12(2)—the Government have put it there as the key priority. That is why we have introduced the ability for the Secretary of State to disclose information in the event of a safety concern, as we discussed.

I am not sure that the new clause achieves what the hon. Members for Central Ayrshire and for Nottingham North want it to. The intent is to establish a UK registry linking together all existing device registries, so that duplication of the entry of information is reduced, and to require the information entered to include the specifics of a device, such as the clinician who implanted it—information that, in the event of something going wrong, would give a clear picture of what happened. Although that is a commendable aim, the existing registries have been established over time and have expanded into different regions, evolving as they go. We have not had conversations on linkages to the registers in various parts of the country and in devolved Administrations. It is right and proper that we pull back and ensure that we have taken in the views of all stakeholders, and done the proper engagement to ensure that we collect the information from registers appropriately. That needs some work, partly due to the differing operating approaches in each registry. I gently suggest that the proposal in subsection (6) that all implanted devices without a specialist registry be logged on a national registry is a little broad at this stage. We perhaps need to talk about that with stakeholders and others.

The new clause also seeks to establish a governance structure, after consultation with a range of stakeholders, on the management of and access to the proposed registry. I suggest that the consultation requirement is out of step with the consultation duty in clause 40, which provides that consultation with those considered appropriate must take place before we make the regulations. It is a little cart before the horse but, that notwithstanding, this is very much the direction of travel. I remain of the view—no doubt we will come to this point—that we must ensure that we do not inadvertently rule out consulting those who ought to be consulted.

The hon. Member for Nottingham North and I have had discussions in this space, and we are united in wanting this idea to get to the right place. I appreciate the careful consideration that was given to the new clause, and I am grateful for it. I would welcome further discussions in the near future.

Matt Western: I am keen to clarify, not having been party to previous debate, what happens with non-medical cosmetic devices implanted by a medical procedure. Should registry for them be part of this consideration? There is a subsequent impact on our NHS when things go wrong.

Jo Churchill: I thank the hon. Member for his intervention. We are not talking about cosmetic devices here, but I very much take his point. If it involves implantation, it is worth talking about, in the round, during consultation; however, many of the cosmetic issues he refers to may be temporary—if, for example, a device is inserted and then taken away. The legislation is about implanted devices. Again, it is something that we would talk about and ensure that we had consulted on, but for the purposes of the Bill, we are specifically looking at medical devices, and the definition of them.

As I said, I welcome discussion with those interested in these matters, particularly as we look forward to Baroness Cumberlege's review, which is coming very shortly. On that basis, I ask the hon. Members for Central Ayrshire and for Nottingham North to withdraw the motion, but I will commit to following up with arrangements to have those discussions in a timely fashion.

Alex Norris: We are in vicious agreement on this point. The new clause provides a possible destination, but through conversations and the expertise of colleagues, we may end up going in a similar but different direction. It is right that we start with the goal in mind and then work to where we get to. I think there is real potential in this area. As the Minister said, my hon. Friend the Member for Warwick and Leamington made a very important point, because the principles are very similar. There may be scope to include the areas that he mentioned also.

I thank the Clerks and you, Chair, for your support in this process. We have had some very good discussions, and laid the groundwork to do even more. I beg to ask leave to withdraw the motion.

Clause, by leave, withdrawn.

Question proposed, That the Chair do report the Bill, as amended, to the House.

The Chair: Before I put the final question, I thank all Members, particularly the Minister and the shadow Minister, for the way they have conducted themselves throughout the proceedings, which have been a pleasure to chair. I also thank the two Clerks and the *Hansard* reporters for their hard work.

Question put and agreed to.

Bill, as amended, accordingly to be reported.

10.25 am

Committee rose.

Written evidence reported to the House

MMDB15 Association of British HealthTech Industries (ABHI)

MMDB16 British Veterinary Association (BVA)

MMDB17 Pharmaceutical Services Negotiating Committee (PSNC)

MMDB18 National Pharmacy Association (NPA)

MMDB19 Royal Pharmaceutical Society (RPS)