PARLIAMENTARY DEBATES

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GENERAL COMMITTEES

Public Bill Committee

MEDICINES AND MEDICAL DEVICES BILL

Third Sitting

Wednesday 10 June 2020

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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)