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Public Bill Committee

MEDICINES AND MEDICAL DEVICES BILL

Second Sitting

Monday 8 June 2020

(Afternoon)

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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

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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)