HOUSE OF LORDS

Terminally Ill Adults (End of Life) Bill Committee

Corrected oral evidence

Wednesday 5 November 2025

10.15 am

Watch the meeting

Members present: Lord Hope of Craighead (The Chair); Baroness Berger; Baroness Berridge; Baroness Finlay of Llandaff; Lord Goddard of Stockport; Lord Goodman of Wycombe; Baroness Hayter of Kentish Town; Lord Markham; The Lord Bishop of Newcastle; Lord Patel; Baroness Scotland of Asthal; Baroness Smith of Newnham; Lord Winston.

Evidence Session No. 10 Heard in Public Questions 121 - 136

Witnesses

I: Rachel Arrundale, Interim Director of Partnerships, Medicines and Healthcare products Regulatory Agency; Greg Lawton, barrister and pharmacist; Laura Wilson, Director for Scotland, Royal Pharmaceutical Society.

Examination of witnesses

Rachel Arrundale, Greg Lawton and Laura Wilson.

Q121 **The Chair:** Welcome to the 10th session of our inquiry into the Terminally Ill Adults (End of Life) Bill. We are joined at this session by Laura Wilson, Rachel Arrundale and Greg Lawton. You are all very welcome and we look forward very much to what you have to say to us in your evidence. We would be grateful if you would each introduce yourself briefly the first time you speak. We have written statements from two of you. If you would like to add anything briefly, do so, but I am anxious that we should get to questions rather than prolong things with anything else you may have to add.

This meeting is being broadcast and a verbatim transcript will be taken for subsequent publication. It will be sent to you to check for its accuracy and we would be very grateful if you would let us know if there are any errors in it that you think we should be aware of. The last thing I must say is that a list of members' interests is published on our website.

I wonder whether I can begin by asking Laura Wilson whether you would be kind enough to introduce yourself and add a few words, if you would like to add any.

Laura Wilson: Thank you to the committee for the opportunity to give evidence today. I am the director for Scotland at the Royal Pharmaceutical Society. I have been a pharmacist for over 20 years, working in a variety of settings, but my main background is community and addiction services.

The Royal Pharmaceutical Society itself is the professional leadership body for pharmacists and pharmaceutical scientists. Our members work across health and care settings. We take a neutral stance on assisted dying and our written evidence sets out our position on a number of areas, including conscientious objection and criminal liability. We believe that there are a number of considerations that still need to be given to areas that will affect pharmacists, such as the supply mechanism for the approved substance; the overall medicines governance; and the opt-in register for health professionals. We would encourage further consultation with professional bodies on how the assisted dying Bill will work in practice, including on key issues such as regulation, standards, guidance and training. Thank you very much.

Rachel Arrundale: I would like to thank the committee for the opportunity to provide evidence on behalf of the Medicines and Healthcare products Regulatory Agency. The MHRA is an executive agency of the Department of Health and Social Care and operates as part of Government.

The MHRA's remit is to ensure medicines, medical devices and blood products in the UK are effective, acceptably safe and produced to high-quality standards. While we are part of Government, our regulatory decisions are independent. We authorise medical products, so giving

approval for products to be placed on the market. However, whether these products are used by the NHS or clinicians and in which ways is for other bodies, such as the National Institute for Health and Care Excellence, the NHS and professional bodies.

As the interim director of partnerships in the MHRA, I am responsible for the development and management of our national and international partnerships, for the development of new legislation, and for regulatory policy, which is why I am before you today. I work closely with expert colleagues across the agency who are responsible for regulatory decisions and the detail of legislation in their areas.

As you are aware, the Government are neutral on the topic of assisted dying and the passage of this Bill. That applies to the MHRA also. I am happy to be here today to help in any way that I can.

Greg Lawton: Good morning. I am a barrister and a pharmacist. I take no position as to whether facilitated suicide should be available in England and Wales. However, my view is that, if it is to be made available, the Private Member's Bill process being used is an unsuitable way of introducing it.

The legislature, through individual parliamentarians, has the task of serving the interests of the public. It is difficult, as an outsider, to see how that can be done adequately without first asking the public what those interests are. The Bill is shapeshifting. It is changing seismically from one stage in the legislative process to the next, indicating that Parliament is not sure what the Bill should say, if anything. All the while, the developments are not underpinned by wider public consultation.

The Bill's drafting is inadequate. In parts, it is antithetical to the UK constitution. It fails to maintain an appropriate separation of powers. There would be serious difficulties in advising clients on how it would be interpreted by the courts. From a pharmacy perspective, one would want to know that patients' interests have been fully considered.

One key consideration is the drug development and supply process. The drugs being used would not be medicines, if being used to facilitate suicide. Such a purpose is not encompassed by the definition of "medicinal product" in the Human Medicines Regulations and case law. Naturally, when one thinks of a medicine, one does not think of a drug that is designed to cause death. That means that legal provisions pertaining to medicinal products will not apply.

Clause 37 has been the answer to that, leaving everything to the Secretary of State to decide, without any framework in primary legislation for what would be an entirely new process. It leaves a substantial blind spot for Parliament. What would the Secretary of State decide? Would supply be on the NHS, privately, or both? Would it be made through pharmacies, dedicated centres, or both? Under what conditions and circumstances would it take place?

The Chair: Mr Lawton, I am sorry to interrupt you, but I do not want you to go on too much longer because we really have to move to questions.

Greg Lawton: That was the end of it. Thank you for the opportunity to speak and I look forward to the questions.

Q122 **Baroness Finlay of Llandaff:** My question is primarily aimed at Rachel Arrundale, but the others might wish to come in. As we have already heard, a medicinal product is defined as something for treating or preventing disease in humans or that may be used for diagnostic purposes, whereas a poison is a substance capable of causing the illness or death of a living organism.

I wondered how you will regulate these products, particularly when some of them are not licensed for human use in the UK. The public out there think this will be a Hollywood death. They think it will be just one tablet. Could you explain the quantity of drugs that would need to be taken, where the evidence is as to how they act, how they bring about death, how they are ingested and, indeed, how long it takes from ingestion for the person to die?

Also, the Bill talks about a device. I wondered what device you have in mind that would be regulated. I would like to come back to that in a moment. Perhaps the first part will be about the drugs.

Rachel Arrundale: I should first start by saying that, if the Bill becomes law, whether the MHRA is involved in regulation is a matter for Ministers. That is not a decision that has been taken as yet. It is not clear whether the MHRA would be involved in regulation of approved substances or devices to be used in assisted dying. That would be a decision for Ministers, if the Bill becomes law.

In terms of the definition of medicinal product, that is a really difficult question. Dr Lawton has also referred to it in his evidence. I think, though, if we look at the Bill, the substances to be used in the process are defined as "approved substances" and they will be defined in regulations. There will be a list of them in regulations and the Secretary of State must make that list. The question of "medicinal product" in the HMRs, in a way, does not apply to that. Clause 37, as you know, lists the detail of regulations that can be put in place to provide a regulatory framework for those substances.

In terms of the clinical questions that you have asked, I am afraid I cannot answer those. Those are matters for clinicians and doctors based on the evidence that is available, which is from experience in other places.

Baroness Finlay of Llandaff: Can I come back on that? Are there any medicinal products that do not go through a NICE or MHRA process but are actually approved by the Secretary of State at the moment?

Rachel Arrundale: No. Formally in the legislation, actually, it is the Secretary of State and the MHRA acts on behalf of the Secretary of State. No, the MHRA does that work.

Baroness Finlay of Llandaff: What research would you need to draw on? It has been difficult to find research that shows how these different drug mixtures bring about death and the variation and complication rates. I do wonder what will happen if a person takes only part of the dose. We know that that has happened in some cases because they are drinking a large volume of toxic liquid that tastes absolutely terrible. What happens if they have complications or they should reawaken? Would that be something that would be of concern to the MHRA or any other regulatory body?

Rachel Arrundale: Again, I will just refer to my previous comment on that. The decision has not been taken about whether the MHRA will be involved.

I have spoken to colleagues who work on the assessment of current medicinal products about this. The situation would be that we would look at all the evidence that would be available. That would start from evidence about how the product was made, non-clinical data, lab studies and knowledge about the substances in use. It is our understanding that in most parts of the world the substances in use are in fact medicines licensed for other purposes or other indications in the UK. There may well be quite a lot of clinical data available about those substances in use for other reasons. We can also draw on experience from other jurisdictions where they have been used. A lot of information may well be available.

If I may just finish, my colleagues would assess that incredibly rigorously, as they do in all their other work. If there were any suggestions that they were not safe or effective for the purpose intended, the substance would not become an approved substance. That is speaking hypothetically. I must say, again, that no decision has been taken about the role of the MHRA.

Baroness Finlay of Llandaff: I just wonder whether your colleagues have any comment that they would like to make. One of my concerns for pharmacists is that, if this is dispensed in community pharmacy and there has been an error, where the liability would lie, particularly if the dispensing was actually done by a pharmacy technician under authorisation from a pharmacist.

Laura Wilson: There needs to be a decision about how the supplies are made; what protocol is used; as Rachel has said, whether it is an existing licensed product that would then be used in an unlicensed way; and what authorisation is given for that to happen.

We do think that there is a potential issue with that supply mechanism and the responsibilities because currently, as the legislation stands, a pharmacist will supply a prescription to the patient. That cannot happen because of the clauses within the Bill. They have to supply it to the

doctor. There will need to be exemptions made, if the retail supply is the route that is gone down.

On where the liability lies, we know that pharmacists do retain some of the liability for the provision of substances on prescription to patients. I think there would have to be a process by which the pharmacist is satisfied that what they are supplying is the approved substance, that the agreed protocol that has been given is compatible with what the patient wants to happen, and that the processes after that are followed and rigorous to make sure that that is all recorded.

The Chair: We really have to move on. We have two seconds for Greg Lawton to say something—very briefly, please.

Greg Lawton: Thank you. In respect to the licensing, I think the metrics would be completely different. I assume a regulator would be looking at how quickly it causes someone to lose consciousness, how quickly it brings about death and what the percentage likelihood of death is. Those are completely different to the metrics you would be looking at if you were licensing a medicine. Some of the metrics may be similar.

In respect of supervision by pharmacy technicians, I would have some concerns about that. In respect of the drug being supplied in error, yes, that is a possibility, but it is not clear from the Bill whether the intention is that it would be supplied from pharmacies or dedicated centres. It is not clear whether there would be other drugs on the shelf in respect of which it could be supplied in error.

The Chair: Forgive me. I have to stop you there. Before I move to the next question, there are some noises from mobile phones. Could you please be sure your phones are on silent so we are not interrupted by that?

Q123 **Lord Markham:** Again, this is mainly to Rachel. I am just trying to understand the process. I think I heard you say—I assume it would be the same if you are reviewing cancer drugs or anything else—that you review all the evidence from around the world and, based on that evidence, you regulate whether a drug should be approved or not. In this case, you would be doing that in the case of assisted dying drugs. Is that right?

Rachel Arrundale: Again, there has been no decision taken about whether we would be involved so in a sense this is hypothetical, but, yes, we would draw on that experience. If the MHRA is not the designated body, we would be happy to offer that expertise anyway. Yes, it would be the same sort of rigorous assessment.

Lord Markham: Generally, if we draw on what we do with cancer and other drugs, it is the clinician in the medical setting who decides. Once something is on the approved list, it is up to them to decide then how those substances are used. Is that correct?

Rachel Arrundale: Absolutely, yes. I was trying to draw that out in my opening statement. What the MHRA does is to approve medicines and other medical products for use, but that does not mean that those need to be used. It is, at that point, up to clinical judgment.

Lord Markham: Then it is over to the NHS.

Rachel Arrundale: Yes, it is over to the NHS and clinical judgment.

Lord Markham: In any of those areas, are there any ones where Parliament has a role in that? I think not.

Rachel Arrundale: I cannot think of one. I am always worried about being definitive, but I cannot think of one.

Lord Markham: No, I cannot think of one. If you take cancer, it is not like you are suddenly saying that Parliament should be opining whether this cancer drug should be used. I say this as a parliamentarian who knows not very much about this subject. Do you believe that there is a case for Parliament to be involved in these substances or do you believe that the current process that exists, where Parliament is not involved and it is left to the experts and the NHS, is the right one?

Rachel Arrundale: I would have to say that that is a matter for Parliament and the Bill sponsor to decide. It is not for the MHRA to decide.

Lord Markham: This is a question to you, Greg. Is there any other drug where in primary legislation Parliament has a role in prescribing it?

Greg Lawton: I would have to come back to you on that to understand whether there is anything that is put in primary legislation. In my written evidence, I have not suggested that the drugs themselves should be prescribed in primary legislation by Parliament. That is potentially a matter that could be left to secondary legislation and regulation. At the moment, as has been pointed out, there is very little evidence for how these drugs are being used in other countries. At least the evidence is limited.

Lord Markham: I do not think it is limited, is it? I believe other countries have been doing this for years, if not decades, with thousands and thousands of people. I guess this is all evidence that you would be drawing on, Rachel. We have a wealth of evidence from countries all around the world involving thousands upon thousands of deaths. You would be bringing your expertise to bear and drawing on that evidence.

Rachel Arrundale: Yes. As you have said, as with cancer drugs, we would look at all the evidence that was available.

Q124 **Lord Goodman of Wycombe:** If I may, I want to follow up the question that Lord Markham has just asked. There is a line of argument that we have heard before in the committee, which you have just put very well, that the decision about the approved substances should be left to

experts. It is the case under the terms of the Bill that it will not be experts who take the decision; it will be the Minister. In other words, one politician will take the final decision rather than politicians debating this matter on the floor of the Commons. That is a fact, is it not?

Rachel Arrundale: Is that about Clause 27, which says that the Secretary of State is required to provide the list?

Lord Goodman of Wycombe: I am referring to Clause 37 of the Bill. The decision will be taken by the Secretary of State and then regulations will be presented.

Rachel Arrundale: Yes. The regulations that the Secretary of State is required to put down in Clause 27 to specify the list of approved substances, and then in Clause 37, would be subject to the scrutiny of Parliament. Under the terms of the Bill, consultation is also required with suitable expert bodies, including colleagues at the table today. While of course the duty is given to the Secretary of State, the regulations would have to be consulted on and then would come to Parliament for scrutiny.[1]

Lord Goodman of Wycombe: Both the Delegated Powers Committee and the Constitution Committee—those are two committees of this House—recommended that the matter be considered on the Floor of the House. I think I already know the view of Mr Lawton on this, although he is welcome to elaborate. Do the other two witnesses think the committees are mistaken?

Laura Wilson: We would encourage, regardless of where it is decided, that it is done by a panel of experts who are giving advice on the best substances to use based on the real-world evidence that we have.

We would just exercise maybe a note of caution about it being in primary legislation around things such as supply issues and the requirement potentially to have to change the approved substance at short notice, if there are issues. We have seen that in the past with, for example, diamorphine in palliative care, where protocols and things had to be rewritten at short notice because there was a worldwide supply issue. I suppose that would just be a note of caution. It is not insurmountable.

We would also recommend that there is perhaps a limited choice of substances, which would enable ongoing research and more rigorous service evaluation, obviously while maintaining that patient choice.

Lord Goodman of Wycombe: Mr Lawton, do you have anything to add on this point?

Greg Lawton: It is something that I think would certainly need very close scrutiny, if the Bill was introduced, at least at the outset. For example, is the intention to design a single-dose product or is the intention that a person is going to have to take, for example, 80 to 100

[1] Note from witness: Rachel Arrundale subsequently clarified that she had spoken in error and that there is not a consultation requirement in the Bill as drafted.

capsules or tablets of a product in order to facilitate their own suicide? The monitoring of what happens during the process of death will be particularly important.

As to whether it is in primary or secondary legislation, in respect of medicines that is primarily dealt with through the MHRA. The licensing is done through the MHRA. There may be examples in primary legislation of where a medicine is specifically identified, but, in respect of the licensing, that is done through the MHRA. I expect that, in respect of these products, if it is not the MHRA but a different licensing authority, the process would be ultimately similar to that.

Lord Goodman of Wycombe: Of course, it is a feature of the Bill that we do not know whether it will be the MHRA.

Greg Lawton: Indeed, that is one of the issues with the Bill. There is no framework that sets out how that is going to happen.

Q125 **Lord Winston:** I have two very brief questions. First, you have talked about patients who are given a drug not handling it, but is that not very common in the treatment of patients? I can think of drugs that I have had in the last month, which I had no control over beyond accepting the fact that the doctor was giving them to me for my treatment. I certainly would not have been allowed to handle them because they would have been regarded as being dangerous.

Secondly, are we not in a position to learn a great deal more from what is already going on in other countries? It seems to me that we are talking in isolation here. There is a vast amount of medical literature. People are eager to publish these sorts of details. Could you perhaps answer that question?

Laura Wilson: We would suggest that there is a wealth of knowledge and that that should be drawn upon worldwide, particularly when making decisions about what protocol should be used and the evidence that is available for that. There is a responsibility, if this goes ahead, to commit to a robust research and evaluation process so that, when we come to review the services that are being offered, everything possible is being done to allow the best outcome for patients and the best experience for patients.

Lord Winston: Thank you for that answer.

Rachel Arrundale: I think your question was about medicines in use, which is not for me.

Greg Lawton: I would agree with what my colleague from the Royal Pharmaceutical Society said. If the Bill was introduced, it would be necessary to ensure that a substantial amount of research was done in the UK.

Lord Winston: There are many drugs that are not researched in the UK, but we use them regularly all the time, with due respect. We accept data

from other countries. Certainly, we might need to check them sometimes, but I can think of numerous drugs on the market at the moment that are, in fact, not the result of British research—indeed, increasingly so.

Greg Lawton: One thing I am not sure of is, where facilitated suicide is available in other countries, whether they are treating those products as medicinal products. What licensing regime applies in those countries for the drugs being used to facilitate suicide? That is something that I am afraid I cannot advise you on.

Q126 **The Lord Bishop of Newcastle:** Thank you for your time today. I have a couple of questions. The first is around the theme of conscientious objection, please, to Greg Lawton and Laura Wilson. The Royal Pharmaceutical Society and others have highlighted the importance of ensuring that pharmacists who hold a conscientious objection are protected under the Bill. Are pharmacists currently sufficiently protected under the conscientious objection clauses? Would pharmacies benefit from the opportunity to opt out of the provision of assistance on an organisational level?

Laura Wilson: Yes, we believe there should be an opt-in for any healthcare professional who will be involved in the process. We think that is in patients' interests and in the interests of healthcare professionals to know exactly who is going to be involved in the process around that individual. We welcomed the "no duty to participate" and we welcomed the inclusion of a clause around supply, which then protects the pharmacists.

We possibly would strengthen some of those to clarify the difference between the provision of assistance and participating in the provision of assistance. There are two separate clauses that seem to be used within the Bill. Where one is mentioned, the other should potentially be mentioned to offer that overall clarity on where conscientious objection and criminal liability can be afforded.

Greg Lawton: It is an interesting question, if there was an opt-out process, whether that would work at an organisational level or an individual level. In respect of what happens currently, there is provision in standards issued by the General Pharmaceutical Council as to conscientious objection. That seeks to strike a balance between religious or personal belief, for example, and the needs of a patient. This would be a new process and might invoke a greater prevalence of people seeking to rely on conscientious objection, so that would need to be re-examined.

The Lord Bishop of Newcastle: Just briefly, if I may, I have one more question to all three of you. It just picks up on something that Baroness Finlay referred to in her question, which was about the mention of a device in the Bill. I wonder whether any of you can comment on the question of how a device will deliver a peak level rapidly to ensure deep sedation before the person is paralysed and unable to breathe?

Laura Wilson: Obviously, without knowing what protocols are being suggested, it is very difficult to say. It could take the form of an injection; it could take the form of a device to be used with some form of medicine delivery pump. Without knowing what protocols are being considered, it is very difficult to say how that would be managed in practice.

Greg Lawton: I would agree with that. I was wondering what device the draftsperson had in mind. It would have to be a device that someone was capable of using to self-administer the drug. I am not sure what is in mind there.

Rachel Arrundale: If I could just add, when we are looking at the provisions in the Bill to consider its workability, we think about the wide range of devices that will be used at the time, right from patient positioning devices and bedside frames to syringes, infusion kits and monitoring equipment such as pulse oximeters, through to the sorts of devices that you are talking about. Quite a wide range of devices might be needed during the process. When we are considering the workability of the Bill, those are the sorts of things that we have been considering in looking at those provisions.

Q127 **Lord Patel:** Good morning. Thank you, all three of you, for coming today to assist us. I am grateful to you. Can I start with you, Ms Arrundale, on medicines? In the evidence that was presented—I will refer to it when I find it—about the use of the drug, the Bill's impact assessment stated that it "currently assumes that, in the first instance, the approved substance(s) would not be licensed by the MHRA (Medicines and Healthcare products Regulatory Agency) specifically for the purpose of assisted dying, although this is subject to further consideration if the Bill were to obtain Royal Assent". You already mentioned that it will depend on what the Minister then says and whether MHRA is a regulatory authority.

In your view, do you think that there could be another regulatory body that could do the same function that MHRA is already doing in other medicinal products and devices? In amendment 27, which was presented in the Commons at Report stage by Rachael Maskell—

Rachel Arrundale: Could you just repeat that? There was a loud bang at that moment.

Lord Patel: Yes, that is a problem with this place. It is not the medicines bottles that we use that are being emptied through there. I will repeat.

Amendment 27, which was presented in the Commons Report stage by Rachael Maskell MP, which is not present in the current version of the Bill, would have required the doses and types of lethal drugs to be licensed by the Medicines and Healthcare products Regulatory Agency. Lord Goodman already referred to our own Delegated Powers and Regulatory Reform Committee, which, as he said quite correctly, said this presented a very skeleton form of regulation.

The MHRA does not forbid use of off-label drugs for prescription by individual physicians based on the guidance they may receive, as you already stated, either from NICE or from professional bodies. We have lots of evidence of that. The suggestion is that these drugs, which will not be licensed by the MHRA, would form part of primary legislation as opposed to part of subsequent regulation or guidance. In your view, would that be appropriate?

Rachel Arrundale: There is quite a lot in that. In terms of the MHRA, we have discussed that it is for the Secretary of State and others to consider whether there is any other regulatory body that could take it on. Regardless of that, the MHRA is always happy to offer whatever expertise is helpful.

In terms of the discussion of licensing, I think what the Bill anticipates is a regulatory regime for this purpose. One might imagine that it would draw quite heavily on the existing licensing regimes, but that is not the same as what is set out in the Bill. There will be regulations put forward for that.

In terms of doses and types of drugs, in usual practice, where there is a medicine licence, it would set out the dosage and indication for which it should be used, and all of those arrangements. In terms of off-label use, no, the MHRA does not forbid it. We also do not comment on off-label use of drugs. When a medicine is authorised, it is authorised for particular conditions. It is clear what condition it should be given as treatment for and at what dosage, and so on.

If the medicine is given for another condition because it is thought to be helpful by the doctor or at a different dosage, then that becomes off-label. That is relatively common, I would say, in the NHS. It is neither something the MHRA forbids nor something the MHRA comments on because at that point it goes beyond our regulatory regime.

There was a question about it being in primary legislation and whether it should be in secondary legislation. Again, I would just have to say that is a matter for Parliament and not for the MHRA to decide.

Lord Patel: Would you think it rather unusual to have medicines that are not licensed for the use that they will be used for put in primary legislation? Also, the drugs, medicines or substances that are used may well change.

Rachel Arrundale: I think the Bill is clear on what it anticipates. It provides for a regulatory regime—in a sense, it would be a parallel regulatory regime—for the approved substances to be specified and identified. Then I guess there would be a further consideration for any doctor or medical professional involved about which drugs they would use. I am sorry if I am not directly answering your question.

Lord Patel: No, you are.

Laura Wilson: We work with a lot of unlicensed off-label medicines. Professional bodies and regulators issue guidance for healthcare professionals on the use of those. It is quite robust as to prescribing, supply, use, when to use and when not to use.

In our own professional regulations, one of the main criteria is that we have to establish optimal treatment for the patient. We would have to ensure that the evidence we are drawing on is real-world evidence—maybe not from the UK, but world evidence—and we draw on the best that we can.

We also have to ensure that effective governance is in place. Ensuring that medicines governance is there should give some reassurance that, whatever substance and protocol is decided, ongoing review and service revision would be in place to do that.

Lord Patel: Following on from that—this is a question for you, Dr Wilson—I am well used to how pharmacists improve both the prescription and the management of medicines. From our own experience in Scotland, you know that medicines reconciliation has improved tremendously because of pharmacists' involvement in everyday patient contact.

One of the pieces of evidence that I have read about from other jurisdictions that have introduced assisted dying is that the involvement of pharmacists in explaining to the person who wishes to go down the line of assisted dying what the products are, what the effects might be, what it will do to them and how it could be mitigated has been found to be extremely helpful. For those pharmacists who may be willing to assist in assisted dying, do you think such guidance would be very useful?

Laura Wilson: Yes, the role of the pharmacist within the current Bill is quite clear. However, pharmacists do have an increasingly clinical role with patient contact. That is almost now our bread and butter. Our day job is seeing patients, reviewing medicines and providing real pharmacological input into their everyday treatments. If that was a role that was considered for pharmacists and was enabled by the Bill, it would be very welcomed.

Pharmacists also have, as you say, a massive role in medicines governance. We would advocate for their inclusion in any medicines protocols that were being decided and any medicines management systems that were being put in place to deal with the approved substances within this Bill.

Lord Patel: Do you think the involvement of pharmacists in explaining, like they do now in other regions, what the medicine is, how it works and what it does would be of benefit?

Laura Wilson: Absolutely, yes. Pharmacists are medicines experts, so it makes sense that that would be a role that they were entrusted with and could deliver very effectively.

Lord Patel: My last question, briefly, is to Ms Arrundale. Are there drugs

that are currently used in other medical practices, which may be off-licence for that use but are routinely used, that are some of the same substances that may be used in assisted dying?

Rachel Arrundale: Yes, that is our understanding. The drugs used in other jurisdictions are, on the whole, medicines licensed for other uses in the UK.

Q128 **Baroness Smith of Newnham:** I am going to ask a couple of questions about opting in versus opting out. Obviously, the Royal Pharmaceutical Society has suggested that there should be an opt-in provision for pharmacists. There does not seem to be any similar suggestion for the MHRA. You have suggested that the MHRA would simply do what it is required to do, should this legislation pass. Should there be opt-in provisions for the MHRA as well, and, if not, why not?

In terms also of pharmacists, what role could be envisaged for pharmacy assistants? Is there a question of liability? My understanding is that a recent statutory instrument does now give pharmacy assistants delegated authority in various areas.

Rachel Arrundale: In terms of the MHRA, if it were to take on the role, we are a responsible employer and would take into account colleagues' views about what they want to work on. We are really fortunate to be able to draw on a wide range of very, very expert people in the agency. We would be able to accommodate people's personal views on that.

You asked about provisions. Of course, that is a matter for Parliament, but I think this is something that the MHRA would do anyway.

Laura Wilson: We have called for an opt-in service for pharmacists. We do believe that that is in everyone's interests, even other medical professionals. It would save patients going from pillar to post to try to access the service. It has to be decided how the service is delivered, whether that is as a standalone service or as a business-as-usual service. Obviously, that is not detailed in the Bill. How that would be managed in practice would have to be considered after that was detailed.

With regards to the delegated authority to pharmacy technicians, again, I think that would probably be covered by guidance and standards from the regulator and the professional bodies around whether in this circumstance that was appropriate. We do not speak for pharmacy technicians, so I cannot say whether that is something they would be willing to do. If the authority was there and it was deemed to be safe and effective, then, with new legislation that is coming in, it could be possible. However, there would still need to be a clinical check by a pharmacist on any prescription that is issued.

Baroness Smith of Newnham: Just very briefly, several of my colleagues have asked about international comparisons and the suggestion that other drugs might not have been tested in the UK, but we have taken tests that have been done elsewhere. Lord Winston pointed out that that is quite common.

We have written evidence from Professor Sleeman, who has pointed out that in terms of the issue of drugs for assisted dying—what was the phrase that she used? I do not want to put words into her mouth—there is basically not a single practice where the different jurisdictions say, "We have a similar view". There is a whole set of different approaches in the different jurisdictions. How would you go about assessing other jurisdictions and the types of experience that we might benefit from in those cases?

Laura Wilson: We would recommend that all the available evidence is gathered and the robustness of that evidence is established. Basically, it is important to look at everything that is being done now and draw on the best possible evidence that you can get, and then make a decision as to what protocols you want to go with. It is going to be a challenge, but it is not insurmountable. It has been done before.

We have looked at international evidence for a variety of products before. Some of that evidence will be robust and some of it may not be up to the standards that we would want. We have to make a decision based on what is out there.

What is important then, with whatever we decide to go with or whatever is decided to go with, is that we do really robust gold-standard follow-up and ongoing evaluation to ensure that it is the substance that we want to continue with and not be afraid to change that, if we feel it could be done better in a different way.

Rachel Arrundale: I do not really have anything to add to that. I would agree.

Q129 **Lord Goddard of Stockport:** Thanks, panel, for some interesting takes on the issues. I think the first question is for Laura. It is quite topical. Apparently, today a survey has come out of your membership saying that 54% of your members are in favour of assisted dying. You take a neutral stance on the position, but—I presume that the people who voted are pharmacists—54% of pharmacists now are in favour of assisted dying. Do you think that would shift your position?

Laura Wilson: I would say 54% of respondents are in favour. That survey was run by the *Pharmaceutical Journal*, which is our independent publishing arm. It was done independently of the Royal Pharmaceutical Society.

We did survey our members in 2013 when we first published our assisted dying policy and we actually got quite similar results. At the time it was about 40% for, 40% against and the rest were unsure. At that time, our national boards, which are our elected officials, decided to take the view that, even if one pharmacist was opposed or in favour, and all the rest were the other, we should still support both sides. We declared a neutral stance at that time.

I do not think the survey will change that. Obviously in anticipation of the Bills going through both Holyrood and Westminster, we had discussions

with our national boards and it was decided not to resurvey our members at that time because we would not change that stance anyway.

Lord Goddard of Stockport: That is quite interesting. Talking about the bigger picture, there is a huge amount of evidence at the moment from the USA, Australia and New Zealand—we are hearing from New Zealand this afternoon in our final session—about the dispensing of assisted dying substances. We have had evidence from Dignitas and Professor Michael Dooley. I am just wondering whether you talk to the pharmaceutical industries in these countries. Some of these countries have been doing assisted dying for 30 years. This is not brand new. It might be brand new to the United Kingdom, but, as a principle, it has been going on for years and years successfully. I am just wondering whether you have made those contacts with your brothers and sisters around the world because it would be really helpful to know that.

Laura Wilson: As a society, we do speak to other jurisdictions. We have actually met with Professor Dooley to have a conversation around how their service works and we have spoken to pharmacists offering the service in different countries.

I think our takeaway from those conversations is that it is about the management of risk, having robust processes in place and trying to reduce variation as much as possible to manage that risk. Pharmacists are fantastic at medicines governance and would probably relish the challenge of setting up a service like this with regard to these substances,[2] but, yes, effectively it is about risk management and ensuring the safe and effective use of the medicine in question.

Lord Goddard of Stockport: When this Bill passes, then, you would be reasonably sure that we would have the most robust and safest practices possible, bearing in mind the evidence that we have been able to gather for over 30 years from around the world.

Laura Wilson: I believe that in the UK we do operate with robust medicines governance practices, but that is not to say they are all perfect. I do believe that that ongoing monitoring would be needed to ensure that, where there are improvements that can be made, they are made.

Q130 **The Chair:** Before I open up to supplementary questions from the committee, I wonder whether any of you have anything you would like to add. Laura Wilson, is there anything you would like to add?

Laura Wilson: No, I do not think so. We have covered most of what we set out to get covered. Just with regards to training, we have not touched

[2] Note by witness: pharmacists are regularly involved in setting up new services and the associated medicines governance. This may involve a level of complexity to which many pharmacists are well accustomed. Pharmacists who opt in to supporting an assisted dying service and who have a role in medicines governance would likely be involved in ensuring the service is operated in as safe and effective a way as possible with regard to any approved substance.

on training and I suppose we would like to see mandatory training in all aspects of medicines handling and governance being included alongside that which has already been decided.

From our perspective, pharmacists are in contact with their patients on a regular basis, even in the community. They are sometimes the first and only point of contact. There is a possibility that somebody who is accessing an assisted dying process speaks with a community pharmacist around that and perhaps makes disclosures. We would advocate for training to be available to all healthcare professionals on some level and robust processes for feeding back any concerns that are raised to the appropriate person. When the RCN gave evidence, I know the nurses stated something similar. They also meet patients and may have things disclosed to them that might cause concern. It would be really in patients' interests to be able to feed that back as quickly and effectively as possible.

Rachel Arrundale: Thank you for the opportunity, but, no, I do not have anything to add.

Greg Lawton: To reiterate, there have been a few mentions of the substances being medicines. My view is—I set out my reasoning for that in my evidence to the Commons Select Committee—that they would not come within the definition of medicines. That is not an unusual concept. For example, if heroin is used on the street, that is not referred to as a medicine. When it is administered as diamorphine in palliative care, it is referred to as a medicine. The purpose for which a drug is used determines its status.

In respect of the use of the drugs for bringing about death, they would not be described as medicines. Terms like "use of off-label medicines" or "unlicensed medicines" lose relevance because they would not be medicines at all.

Q131 **Baroness Finlay of Llandaff:** I have two really quite different questions. One is for Laura Wilson. You talk about disclosures, but, from the way that the Bill is written, it does not seem as if you would have an ability to provide information to the co-ordinating doctor. I am just thinking about someone who comes in and suggests that their family want them to go down this route or whatever because they often chat to local pharmacists.

You talked about safety. We know that at least nine people in Oregon have reawakened and seven in California. I just wonder how you would define safety. With other drugs, such as the cancer drugs, that were referred to, there are trials and there is a lot of scrutiny in different stages looking at adverse effects and complications. That is all published in peer-reviewed journals.

As the Canadian MAID protocol concedes, there is no peer-reviewed literature to guide best practice in compounding these—they use the term—medications. I just wonder where you have found the peer-

reviewed literature to support the fact that, as is being suggested, because these combinations have been used for decades, they would fit your criteria of safety. Sadly, we know that people have been using massive drug overdoses for many decades to take their own life in different situations, but those are not combinations that anyone in any of the healthcare professions would document or provide advice on at all.

Laura Wilson: I suppose we can only go with the evidence that is available and make a decision based on that. We would suggest that that should not be an individual decision. It would have to be a panel or committee of experts that is reviewing that to ensure it meets whatever standards they set.

Obviously, it is very difficult to say what evidence there is when we do not know what protocols and things we are talking about, but certainly it should not be one individual making those decisions. It should be up to a panel of experts.

Baroness Finlay of Llandaff: Can I ask Mr Lawton about the evidence? Have you seen evidence in peer-reviewed journals of how these different combinations, of which there are many, work?

Greg Lawton: I have read some articles, but I have to say I think the evidence is relatively limited when one compares that to the evidence available for the use of medicines. You would be looking for, as I mentioned earlier, different metrics. How quickly does the person lose consciousness? If they have to take 80 to 100 tablets or capsules, can they do that before they lose consciousness? What is the likelihood of it finally killing the person or the person awakening? How have the studies been conducted? I would want to look in great detail at how that has been done in other countries where facilitated suicide is an option.

One of the difficulties, I think, is in doing clinical trials for a particular purpose. In humans, you would have to do that while someone was taking it for the purposes of facilitating suicide. You would have to have their permission to observe that, to ask them questions at the time and to report on that. I am not sure to what extent that has been done with different drugs and different combinations of drugs. I think those are serious questions that ought to be asked.

Q132 **Baroness Berger:** Can I just get a final clarification on this question? The distinction is that medicines and drugs rightly go through various clinical trials that the MHRA will be well accustomed to. Can I ask whether any of the panel members are aware of any trial or observation data available from any other jurisdiction on any of these drug mixtures that have been used in other countries to facilitate assisted death?

Laura Wilson: We do have a list of the evidence. I do not have it with me today, but we do have a list of the evidence that is available.

Baroness Berger: Is any of that specifically trial or observation data?

Laura Wilson: From my knowledge, I do not believe an actual clinical trial has been done. In my opinion, that would be quite a difficult thing to do, given that the outcome is death. We are certainly not of the opinion that what we understand as a clinical trial would be appropriate.

Rachel Arrundale: Given that the Government are neutral on the Bill, policy implementation questions will follow, if the Bill becomes law. At that time, we would undertake work to assess what evidence is available.

Greg Lawton: The papers that I have read have called for more evidence on that rather than providing robust evidence. I am not saying that there are not such papers, but the ones that I have seen, certainly, have called for more evidence.

Baroness Berger: Can I ask my second question?

The Chair: I have four others to fit in and I would like to fit them in, please. We had better move on.

Q133 **Baroness Scotland of Asthal:** Just from what all of you have said, a problem we have is the lack of specificity in the evidence that we need to make these decisions. You have all said, "We don't know" and, "It's a matter for the Government". Is it right that one of our problems is a lack of specificity?

Laura Wilson: I think it is a lack of evidence that we would consider to be of the gold standard in the UK. We have real-world data and real-world evidence from other countries. It is whether a panel of experts felt that was robust enough to make a recommendation off.

Baroness Scotland of Asthal: We are not there yet.

Laura Wilson: I suppose that is my position.

Baroness Scotland of Asthal: I will ask you a second question. The multidisciplinary assessment that we have now inures to the benefit of the patients we seek to care for because you have the nurses, the pharmacists, the doctors and others bringing information together so we get a whole picture of the person. The position of this Bill asks only for the doctor's view without necessarily having the benefit of what the family knows, what the pharmacist knows, what the nurse knows or what others know.

Is that a safe process to make an accurate assessment as to, first, the person's state of mind or, secondly, whether they are or have been induced, coerced or pressured into making this decision?

Laura Wilson: I suppose it is not for me to comment on the robustness of the process outlined in the Bill. I mentioned earlier that it would be welcomed if there was a mechanism by which other healthcare professionals could raise concerns if they were brought to them in another setting. That certainly to me would be a safeguard that could be put in place. I do recognise that the commissioner, when they are

reviewing the cases, can call on other people as they see fit, so I suppose that potentially could be an opportunity, although it would be time-consuming to hear from other professionals involved in a patient's care, particularly complex patients who may have input from a variety of healthcare professionals. But I suppose, to the crux of your question, it is not really for me to say whether the process is robust or not.

Q134 **Baroness Hayter of Kentish Town:** Just as a comment, talking about taking 80 to 100 pills I think is a bit of a red herring. Australia manages it in a 30-millilitre dose, which I think is equivalent to a single of Scotch, which segues it nicely into Ms Wilson. I have a couple of questions. I am open-minded about whether it should be an opt-in or opt-out, but I am slightly surprised why this would be different from, for example, the morning-after abortion pill. I understand that the General Pharmaceutical Council has guidance on this, which does allow a professional not to participate in giving out particular substances, although they need to take steps to make sure that the person asking for it is the centre of their decision. I assume, therefore, you signpost to someone else if you are in that position.

Is this so very different from a morning-after abortion that you would actually want something different in legislation, rather than what seems to work—from what I understand—quite well with these other things?

Laura Wilson: I suppose the morning-after pill is time-sensitive, and to try to improve access as far as possible it operates on an opt-out service, so a pharmacist can decide not to supply if they feel they do not want to and signpost somewhere else appropriate.

RPS feels that this is of such gravity and the ongoing involvement and preparation that would be required for the person to access this service, as well as the robust training that would need to be in place for someone to undertake the medicines governance and medicines management of any approved substance or protocol, would be such that we would need to ensure that the person who was working that day, in whatever setting is decided upon, actually had chosen to take part in this. It also gives clarity to other healthcare professionals about who will and will not take part in the process.

Baroness Hayter of Kentish Town: For some people, abortion would be more serious, because we are talking about people already dying. We are talking about when they have already been through quite a lot of stages with two GPs, with the panel and all of that, so there is also a bit of a time constraint with this, for someone already dying.

Laura Wilson: We feel the training that is involved in this process should be more robust and therefore form part of the opt-in service.

Baroness Hayter of Kentish Town: Could I ask a second question? I think in what you submitted to us—I have so many pieces of paper—you seem to want a legal requirement for patients to pre-register their wish with their own GP to have assisted dying as an option in the later stage of

their lives, if they were then to fit the criteria. Presumably, if I registered with a doctor at the age of 30 or something, you would want me to have to register at that stage. At 30 you never think you are going to be ill, never mind anything else. Until it becomes an issue, how would you have pre-registered with a GP when you never thought you would be in that position?

Laura Wilson: I can see your point and it is a good question. It is more just to start the conversation.[3] It could be that that is just an initial note of interest, whether that happens when you are 30 and you know that that is how you would want to end your life at some point, or whether that is when your diagnosis is made. It would be entirely up to the patient, but it is really just that.

Baroness Hayter of Kentish Town: Sorry, you say it is a legal requirement for them to pre-register.

Laura Wilson: That is just one of our recommendations. It is absolutely not something that we believe should be set in stone as part of this Bill.

Baroness Hayter of Kentish Town: So you would not want that in this Bill. I mean, it did slightly worry me that I had not registered with my GP when I did it 40 years ago.

The Chair: We have so many on this supplementary list. Baroness Berger, I am sorry I interrupted you. You want to put another point, as quickly as possible.

Baroness Berger: The second question I had has disappeared off my screen. I am sorry; I will have to come back.

Q135 **Lord Patel:** Dr Wilson, thank you very much for your comment about the randomised trial issue. I agree that normally we would rely on solid evidence of randomised controlled trials—Ms Arrundale, you will agree with that too—before medicine is approved for licence or not. There are circumstances where a medicinal product cannot be subjected to randomised trials because the patient population is different and one cannot randomise one to the other because you might end up with harm. There are circumstances where we would stop the trial because the benefits are quite obvious, but, in a situation where we cannot subject it to randomised trial, we rely on observational studies. The bigger the observational studies, the better the evidence. Unless we have that population that is subjected to the same medicines or substances, we cannot perform and put value to their observational studies. Would you agree with that?

[3] Note by witness: RPS Policy was written in 2013 and updated in 2024 prior to the publication of the Westminster Bill. On reflection, the legal requirement mentioned in our policy is akin to the first declaration currently referred to in the Bill and we are not suggesting an additional step be required. This policy is due for review and it may be the language is changed to more accurately reflect that of the current bills.

Laura Wilson: Any research that is done is valuable, but we only have the research that is available in other countries, because the service is not available in this country at the moment.

Lord Patel: Dr Lawton, you spoke, and correct me if I am wrong, about the terminology we use in terms of drugs, medicines or substances. For instance, you said heroin on the streets is heroin, but diamorphine in clinical practice is diamorphine. By the way, I did prescribe it as heroin, not as diamorphine, but that is neither here or there. There are substances we use that are commonly used outside, for instance cannabis. Cannabis oil is used for treatment too. Would you agree that nomenclature of substances does not define whether they are therapeutic or otherwise?

Greg Lawton: The point I was making was to illustrate the principle that the purpose for which a substance is used determines its status. It determines its status as to whether it is a medicine or not. When a drug is being used to end life, in my view it is not a medicine, because it does not fit within the definition of medicinal product.

Lord Patel: How would you define mifepristone?

Greg Lawton: Well, I think one can look at the principle from the point of view of what a medicine naturally means to you. It means a substance that is used to treat or heal, or to relieve symptoms. It would be somewhat Orwellian to say that a medicine is a drug used to bring about death.

Lord Patel: Because you are a pharmacist, would you agree that mifepristone is used more widely for the purposes for which it was not licensed?

Greg Lawton: You are referring to off-licence use as a medicine, but that is different from using a drug to bring about death. When it is used to bring about death, for the reasons I set out in detail to the Commons Select Committee, it does not fall within the definition of a medicinal product. It has been referred to as a medicine, but in my view it should not be referred to as a medicine.

Q136 **Baroness Berger:** If we take one jurisdiction where assisted death takes place, Oregon, we know that in that locality annual complication rates have been as high as 15%, including difficulty swallowing, drug regurgitation and seizures. Can members of the panel set out your understanding? What would happen here in the UK if someone started to ingest a drug to end their life and they were unable to take the whole dosage necessary, because perhaps the taste is so bad? We have heard about tastes of petrol. What if they could not take the volume of drug, depending on what drugs are selected for consumption in this country? What if in fact someone changed their mind? What would happen in that instance? Would the individual still die? How should this scenario be dealt with in an NHS, a hospice or a home setting? Does the Bill currently have the necessary detail and safeguards in place to contend with this

scenario?

Laura Wilson: The truth is that I do not think we can answer that question without knowing what medicines or what substances are being described. I believe there is mention in the Bill—I could be wrong; it may be mentioned elsewhere—that the co-ordinating doctor should have that conversation with the patient about what interventions they would like. I believe that that is an important conversation that would have to take place.

The panel of experts who have decided on the protocol would hopefully have reviewed what substances they have decided to include within that protocol and have a plan of what could possibly go wrong. They are never going to be able to come up with every scenario, but hopefully they would have planned what could potentially go wrong and the co-ordinating doctor would have had that conversation with the patient so they can make a fully informed choice.

Rachel Arrundale: I am afraid these matters go beyond the remit of the MHRA and I cannot comment.

Greg Lawton: If a person vomits shortly after taking a drug, it can reduce the amount that is absorbed, so it could potentially lead to someone not dying as a result of having taken it. It might still be the case, equally, that someone dies nevertheless, having absorbed enough of it. There is not provision in the Bill that I have seen for a second dose being required. I suppose the intention is to cover that through Clause 37, to leave that to the Secretary of State to decide, "Does the process commence again?" Would there be provision made for the person to obtain the drugs again if they did not die and then still had the intention to do so?

The Chair: I am in the committee's hands. I can run this on further, but that means the next session will have to run into lunchtime. Are you prepared to go later or not?

Noble Lords: No.

Lord Markham: I—

The Chair: Well, I am afraid I really have to bring this session to an end. I am very sorry, Lord Markham. We are under pressure of time, because we have another panel to come in. May I thank you very much indeed for your evidence? I wish there was more time to speak to you, but we have run out of time.

I remind you that the evidence has been taken down and will be in transcript. When you receive it, could you check it very carefully to see that it is accurate and records your evidence completely? If there are errors, please let us know. With that, thank you all very much indeed. I apologise to members of the committee who were not able to come in.