

DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Déardaoin, 13 Aibreán 2017

Thursday, 13 April 2017

The Joint Committee met at 9.10 a.m.

MEMBERS PRESENT:

Deputy Bernard J. Durkan,	Senator Colm Burke.
Deputy Billy Kelleher,	
Deputy Kate O'Connell,	

In attendance: Deputies Richard Boyd Barrett, John Curran, Gino Kenny and Jonathan O'Brien.

DEPUTY LOUISE O'REILLY IN THE CHAIR.

The joint committee went into private session at 9.13 a.m. and resumed in public session at 9.24 a.m.

Cannabis for Medicinal Use Regulation Bill 2016: Discussion (Resumed)

Vice Chairman: The purpose of this meeting is to engage with officials from the Department of Health and representatives of the Pharmaceutical Society of Ireland, PSI, on Deputy Gino Kenny's Private Members' Cannabis for Medicinal Use Regulation Bill 2016. On behalf of the committee, I welcome Mr. Eugene Lennon, principal officer, and Ms Maria Egan, pharmacist, at the medicines and controlled drugs unit in the Department; Mr. Niall Byrne, registrar and chief officer of the PSI; and Dr. Cora Nestor, head of pharmacy practice development at the PSI.

By virtue of section 17(2)(l) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if they are directed by the committee to cease giving evidence on a particular matter and they continue to do so, they are entitled thereafter only to qualified privilege in respect of their evidence. Witnesses are directed that only evidence connected with the subject matter of these proceedings is to be given and they are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person or an entity by name or in such a way as to make him, her or it identifiable. I advise witnesses that any submission or opening statement they make to the committee may be published on the committee website after the meeting.

Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official, either by name or in such a way as to make him or her identifiable.

I ask Mr. Eugene Lennon to make his opening statement.

Mr. Eugene Lennon: I am a principal officer in the medicines and controlled drugs unit in the Department of Health. I am joined by my colleague, Maria Egan, who is a pharmacist in the medicines and controlled drugs unit. I thank the committee for the opportunity to provide the Department of Health's observations on the Cannabis for Medicinal Use Regulation Bill 2016.

By way of background, this Private Members' Bill was published by Deputy Gino Kenny and Deputy Brid Smith in July 2016. Much of the text is similar to that contained in the Cannabis Regulation Bill 2013 published by Deputy Luke 'Ming' Flanagan, though there are important differences between the two Bills. In early November the Minister for Health announced a review of policy on the use of cannabis for medical purposes. He requested the Health Products Regulatory Authority, HPRA, to provide him with expert advice. On 1 December, Dáil Éireann debated Deputy Kenny's Bill. During the debate the Minister expressed his concerns about elements of the Bill and noted he was awaiting the HPRA's report on medicinal cannabis. The Bill passed Second Stage and was referred to the select committee. The Minister received the HPRA's report on 31 January. He published the report on 10 February and announced that he will establish a medicinal cannabis access programme for certain medical conditions. Last month the Minister established an expert reference group which is drafting guidelines to facilitate the prescription, supply and use of cannabis treatments for qualifying patients under the access programme.

The regulation of medicinal products and drugs is currently achieved by an array of enactments, including the Misuse of Drugs Acts, the Irish Medicines Board Acts and the Pharmacy Act, all of which aim to ensure medicines that reach the patient are of an acceptably high quality and are safe and effective for use by that patient. The research, manufacture, marketing, distribution and promotion of medicinal products is regulated by European Union legislation, which has been implemented in Ireland by various regulations and orders. The misuse of drugs framework already defines systems of control for the production, supply, import, export, record-keeping, research and destruction of controlled substances, including cannabis and its psychoactive extracts. It also sets out the criminal sanctions that apply for possession, sale, supply or trafficking in controlled substances, including cannabis.

Members of the committee will be aware that cannabis is currently a Schedule 1 controlled drug under the Misuse of Drugs Act and it is the most widely used illegal drug in Ireland. Cannabis is not an authorised medicine and it has not gone through the normal regulatory procedures for medicines which are designed to protect patients and ensure treatments are supported by good evidence of their effectiveness and safety. It is important to note that while there is a view that there is a legal impediment to prescribing cannabis, it is not the case. The Minister for Health may grant a licence for cannabis, containing THC, where the licence application has been endorsed by a consultant.

The Department is of the view that the current Bill is not necessary and is not in the public interest as it proposes to establish a parallel regulatory process for cannabis and undermines the regulatory frameworks already in place for controlled drugs, medicines authorisation and the operation and oversight of retail pharmacies. The Bill proposes to establish two new agencies, one of which, the cannabis regulation authority, will to a large extent duplicate functions already being carried out by other State agencies, in particular the HPRA and the Pharmaceutical Society of Ireland.

While the Department does not believe the legislation is appropriate or necessary, should the Oireachtas decide to proceed with the Bill, there are a number of issues which we would like to bring to its attention. I have already referred to the cannabis regulation authority which is dealt with in Part 2 of the Bill and our concern that it establishes a parallel system of regulation cutting across the functions of existing agencies. We are also concerned about the reference to the development of a consumer oriented licensing system in section 6(2)(b). Cannabis is not a normal consumer product; it is a controlled drug. We must ensure that any system that is established is patient oriented rather than consumer oriented and that it protects patients and the wider public.

There is a reference to fees in respect of the grant of a retail licence in section 27. Retail licences are confined to pharmacies. It is noted that retail pharmacies already pay a fee to register with the PSI and it difficult to see the justification for this additional fee on pharmacies to support a system of parallel regulation by the cannabis regulation authority. There is also a reference to fees for “signs relating to a licence” in section 27(3). This is a puzzling reference and suggests that pharmacies could be advertising by way of signage that they are licensed to sell cannabis products. In our view, unless it is expected that a very large number of licences will be issued, the fee income is unlikely to meet the running costs of the proposed authority.

Part 3 establishes a cannabis research institute. In the view of the Department, it is not necessary to establish such an institute. There is already a considerable amount of research into the illegal or recreational use of cannabis. If a researcher wishes to conduct clinical trials on cannabis, that is already permitted under existing legislation.

We note that one of the functions of the institute is to encourage employers to review drug-free workplace policies, as provided for in section 12(1)(b). There are good reasons many employers have drug-free policies in place and we are unclear as to why a research institute would encourage them to review these policies.

We also note that it is a function of the institute, in section 12(1), to commission and publish research in the areas of safety, risks and benefits of medicinal and-or recreational use. We are unclear why the institute would be mandated to commission research into the benefits of recreational cannabis. There is a further reference to recreational cannabis in section 41.

Section 23(1) deals with disqualifications for holding a licence on conviction of certain offences. It is noted that trafficking or sale or supply of illegal drugs is not specifically mentioned and that, according to section 23(7), a conviction for possessing cannabis will not disqualify a person from being granted or continuing to hold a licence under this legislation.

The Department notes that in Part 7, it is intended that a doctor will issue a certificate to patients, as provided for in section 32. In the interests of patient safety, we believe that a prescription is more appropriate and that it should include details that are currently required to be present on prescriptions for controlled drugs. The Department notes that the HPRA report recommends that for the access programme, patients should be under the care of a consultant and we would support this position.

The Department is particularly concerned about section 42 which removes cannabis from the Misuse of Drugs Acts. This means that possession, sale or supply of cannabis would no longer be an offence under the Misuse of Drugs Act. Cannabis would no longer be a controlled substance with the misuse of drugs framework. While there are a number of offences created in the Cannabis for Medicinal Use Regulation Bill in sections 8, 16, 17, 20, 21, 22, 23, 27, 31, 33, 34, 35, 36, 37 and 39, I would point out that there are no penalties in terms of fines or imprisonment specified for any of the offences outlined in this Bill.

There are other issues of concern and also technical problems with the Bill, for example, the use of the imperial system rather than the metric system in sections 16, 17 and 33. However, it would take some time to go through the Bill on a section by section basis.

To conclude, the basic position of the Department is that we do not see this Bill as being necessary or in the public interest. Cannabis has not gone through the normal regulatory procedures for medicines which are designed to protect patients. The Bill places the regulation and oversight of medicinal cannabis under a unique and separate legislative and regulatory framework from all other health products. This Bill attempts to circumvent existing regulatory regimes and establish a parallel system for cannabis. Given that there is currently insufficient clinical evidence in respect of the efficacy and safety of many cannabis products we should proceed cautiously. It is the view of the Minister for Health and the Department that at this time, the cannabis access programme is the responsible way to proceed.

I thank the Chair. We will be happy to address any follow up questions.

Mr. Niall Byrne: I thank the committee for inviting the Pharmaceutical Society of Ireland here today to assist in the ongoing scrutiny of the Cannabis for Medicinal Use Regulation Bill 2016. I am the registrar and chief officer of the Pharmaceutical Society of Ireland, PSI. I am joined today by Dr. Cora Nestor, head of pharmacy practice development with the PSI.

I will begin by explaining the role of the PSI as the pharmacy regulator. I will then make

some general points on the Minister's recently announced scheme to provide access to cannabis for medical reasons, followed by some specific points on proposed provisions in the Bill. I will keep my remarks relatively brief and we will, of course, be happy to take questions from the committee.

The Pharmaceutical Society of Ireland is the statutory regulator of pharmacists and pharmacies in Ireland and is established as a public body under the provisions of the Pharmacy Act 2007. The PSI's core mission is to work to protect and promote the health, safety and well-being of patients and the public. The PSI has a range of functions, established under legislation, which together create a regulatory framework intended to ensure the safety of patients and the public as users of pharmacy services. Our functions include maintaining the registers of pharmacists, pharmaceutical assistants and pharmacies or retail pharmacy businesses, which is the terminology used in the Act. We also set the requirements for pharmacists' education, their continuing professional development and for their standards of professional conduct.

As part of our regulatory remit, we inspect retail pharmacy businesses to assess compliance with pharmacy, medicines, including veterinary medicines, and controlled drugs legislation. We have powers to initiate investigations where we have reason to believe there may be serious non-compliance. These inspections and investigations may involve co-operation with other relevant public bodies and may also lead to prosecution of persons and businesses who have committed offences under relevant provisions. In the case of individual pharmacists about whom there is a serious concern, or a complaint made as to their fitness to practice, the PSI can initiate statutory conduct proceedings which, after due process, can lead to sanctions being imposed on individual pharmacists and-or restrictions being placed on their practice. The PSI is, by law, independent in the exercise of its statutory functions. For public accountability purposes, the PSI operates under the aegis of the Department of Health. The PSI is governed by a 21 member council appointed by the Minister for Health.

As the committee is aware, on 10 February the Minister published the report, Cannabis for Medical Use – A Scientific Review, which had been produced at his request by the Health Products Regulatory Authority, HPRa. I know that the committee has previously heard from the HPRa in respect of the report and its specific recommendations. As the pharmacy regulator, the PSI does not have any direct role in the scientific review and approvals process for medicines. However, given the role of the PSI as the regulator of the profession responsible for medicines supply, it is relevant to state that the PSI agrees with the HPRa statement to this committee on 7 March that, "The best outcome for patients is the development of authorised ... cannabis-based medicines where the safety, effectiveness and quality can be assured, and understood by the patient and health care professionals."

In circumstances where cannabis products may be made available to meet specific patient need outside of the normal medicines authorisation process, the PSI agrees with the careful and prudent recommendation of the HPRa report, and the subsequent decision of the Minister, that a controlled access programme be established. The PSI also agrees that the operation of the programme should involve careful monitoring, including the registration of patients, doctors and pharmacists who are participating in the programme.

On the use of cannabis for medical reasons, the PSI also notes the advice provided to the Minister for Health by the Chief Medical Officer, as published by the Department of Health on 6 March 2017. In that advice, the CMO refers to the central role played by doctors and pharmacists in ensuring the safe and effective use of any drug that is prescribed. He goes on to say:

In establishing an access programme for medical cannabis, it is therefore critical that the views of these professionals, through their professional bodies, are considered. Efforts are underway to ensure that the planned access programme reflects those views and that the roles and responsibilities of doctors and pharmacists in prescribing and dispensing cannabis for medical purposes are clarified prior to its establishment.

The Pharmaceutical Society of Ireland, PSI, as the pharmacy regulator, welcomes and supports this engagement process and we are actively involved in the deliberations of the expert reference group which has been established. The objectives of PSI's involvement are primarily focused on ensuring that the access scheme works for patients who are accessing cannabis for medical use under the scheme and that those patients can have their prescriptions dispensed by pharmacists in a timely, effective and safe way.

There are two specific points that PSI wishes to make on the Bill. The role of the PSI is primarily to implement pharmacy and medicines law as enacted. Hence I will leave it to my colleagues from the Department of Health to address in detail the provisions in Deputy Gino Kenny's Bill and what amendments the Department believes may be required, which Mr. Eugene Lennon addressed earlier. I will make two points which are intended to be helpful to the committee in its consideration of the Bill.

As I mentioned earlier, the PSI operates the regulatory framework for pharmacists and pharmacies as prescribed in the Pharmacy Act 2007 and regulations made thereunder. The PSI has been operating these provisions for ten years and our experience is that the regulatory framework is robust and works to protect the public. The PSI believes that the current system of regulation is capable, subject to the views of the expert reference group, of regulating the supply of cannabis for medical use under the controlled access programme. In so far as the Bill proposes that a parallel retail licensing scheme, including additional statutory inspections, would apply to registered retail pharmacy businesses, the PSI would regard this as an unnecessary duplication of existing provisions which are already well-proven in practice.

A central concern for the PSI is to ensure the public can rely on the professionalism of pharmacists and the quality of regulated pharmacy businesses when seeking to have medicines dispensed on foot of prescriptions from authorised prescribers. In so far as the Bill proposes a system of medical certificates as being the basis on which supply would be made by a retail pharmacy business, the PSI is strongly of the view that moving away from the current requirements whereby medicine and controlled drugs can only be supplied on foot of an original and valid prescription, signed and dated by the prescriber, would represent a weakening of the overall regulatory control framework and an unnecessary deviation from well-established practice.

I assure the committee that the PSI, as the statutory and independent pharmacy regulator, takes its responsibilities towards public safety seriously and is committed to ensuring pharmacists and pharmacies can be trusted by patients and the public to provide safe and reliable pharmacy services. The PSI is also committed to the well-being of the public and, in this regard, is playing an appropriate and assistive role in the design and implementation of the Minister's access programme for cannabis for medical use. Once the access scheme is established, the PSI will ensure pharmacies and pharmacists comply with the provisions of the programme and we will also ensure pharmacists are fully aware of their duties and responsibilities to patients under the terms of the programme. The PSI believes that the access programme can operate effectively within the current regulatory framework under the Pharmacy Act 2007 and related medicines and controlled drugs legislation.

I hope my opening statement has been helpful. I thank the committee for its invitation here today and both I and Dr. Cora Nestor are happy to assist further by taking any questions which members of the committee may have.

Vice Chairman: I will take questions from members of the committee, but I have a quick question of my own for Mr. Lennon. In his opening statement, he advised that the Bill seeks to set up a parallel regulatory process and that he believes this undermines the regulatory frameworks already in place for controlled drugs. Would it be Mr. Lennon's view that the existing regulatory framework would be up to the task of regulating cannabis and that the Health Products Regulatory Authority, HPRA, would be able to take on that task?

Mr. Eugene Lennon: The HPRA already issues a range of licences for controlled drugs, including import licences and export licences. Wholesale distributors for medicinal products, including for distribution of controlled drugs, are already registered with the HPRA. The HPRA has a whole range of functions with regard to a controlled drug like cannabis or a medicinal product, which some people would see cannabis as. Those functions are under the remit of the HPRA already. We seem to be setting up quite an elaborate parallel system. We are talking about licences for retail pharmacies here already. They are already registered with the PSI. There is a whole system for this. The only thing not currently dealt with is the provision in this Bill for cultivation of cannabis for medicinal purposes. That is not Government policy at the moment and is the only provision that other State agencies are not dealing with at the moment.

Vice Chairman: Mr. Lennon referred to the Bill seeking to establish a cannabis research institute, and in his opinion it is not necessary because there is much research into the illegal, recreational use of cannabis already. On the cannabis research institute, are there other examples of similar research institutes in this State specific to one product?

Mr. Eugene Lennon: Not specific to one substance or product, but the Health Research Board and National Advisory Committee on Drugs and Alcohol already publish research on uses of cannabis in Ireland. On clinical research, it is possible to get a licence to conduct clinical research into cannabis and there is also clinical trials legislation which allows for trials that would facilitate cannabis being researched for medical uses as well. There is no bar on research on cannabis in the country.

Vice Chairman: We will take questions now. I call Senator Colm Burke.

Deputy Richard Boyd Barrett: Are committee members being called first?

Vice Chairman: Yes. That is convention.

Senator Colm Burke: Mr. Lennon refers in his opening statement to the expert reference group having been established. I presume that will produce guidelines about how this is going to be managed from now on with regard to the prescribing and use of medicinal cannabis. What is Mr. Lennon's view on the timescale for when the expert group will be reporting back? Have we any idea of what kind of structure we are talking about? For argument's sake, I have met a number of people who are using medicinal cannabis at the moment, though not through any regulation. I understand that quite a number of people are in that position. If we have an expert group that gives guidelines, when will that expert group report back? I presume there would be a large number of applications initially. Would it be able to deal with those? What kind of structure is it envisaged will be established to deal with those applications?

Vice Chairman: I will take the questions in groups of three, if the witnesses are agreeable.

I call Deputy O'Connell and then Deputy Bernard J. Durkan.

Deputy Kate O'Connell: I welcome the witnesses. I am a member of the Pharmaceutical Society of Ireland and I have two retail pharmacy businesses registered with the Pharmaceutical Society of Ireland. I am obviously a pharmacist.

I will refer to the access programme before I look at the Bill, and perhaps somebody from the Department could outline this matter very clearly to us. My understanding is - perhaps I have misinterpreted it - that before any of this conversation started in recent times, with the advent of the Bill, the mechanism has always been there for an Irish-registered medical consultant to apply to the Minister for Health for access to a Schedule 1 controlled drug under specific circumstances for a named patient under the consultant's care if the consultant is to dispense and monitor those. There is and always has been a facility for an Irish-registered medical consultant to apply to the Minister before any access programme starts. I would like that to be clarified for the committee.

Senator Colm Burke brought up the issue of the access programme. I would like to know where we are and where we are going with that. Three conditions are specified and my understanding is that it is not just three. There are three now and there would be a view to including other conditions or indications as more data emerge. Will the witnesses clarify the position? The provision is not necessary in light of the fact that people can access this product if they have a proper prescription from the registered consultant.

I have an issue with the Minister for Justice and Equality being listed in the first section as opposed to the Minister for Health. Is it not the latter who has the overriding power?

I have concerns about referring to the cohort of patients who might require this as "consumers". They are patients. Regardless of anything else, this is still a Schedule 1 controlled substance. That is done to guarantee public safety, which Mr. Byrne mentioned was one of our roles.

Deputy O'Reilly referred to research. It is my understanding that there is no barrier to research in that universities can get special exemptions for it. We would never get anywhere if we did not have exemptions, particularly as we could not trial a drug. Will the witnesses clarify the position in that regard?

Offences are listed in section 8, the final line of which reads, "is guilty of an offence." Perhaps I have missed it and someone from the Department will guide me, but is there a penalty - the word "penalty" is sensitive for some of us - for these offences?

As a pharmacist and a Member of Dáil Éireann, I have concerns about the functions of the institute listed under section 12(1)(a)(i), which refers to "medicinal and/or recreational use". It is strange that a Bill with "Medicinal" in its Title swings into a recreational format. The so-called benefits of recreational use are a different conversation to the medicinal framework.

We have a very robust system of assessing the safety risks of medicines. In my academic days, it used to be referred to - perhaps this is no longer the case - as the Swiss cheese theory. We do not want the holes to line up and something to slip through that would damage patient health. This subsection circumvents the rule that all of us in the field have worked hard to get right in order to protect patient safety. Any shifting of those regulations could leave us with the Swiss cheese effect even though our first job is to do no harm.

The systems regulating the sale and supply of controlled drugs are robust and pharmacists must comply with the regulatory framework. The public may not know it, but we take controlled drugs seriously. We cannot have baskets of them lying on the counter. Every tablet must be accounted for. If one goes missing, the Garda needs to be called. The destruction of controlled drugs must be monitored. Let us say that cannabis is moved from being a Schedule 1 to a Schedule 2 drug. Speaking in a professional capacity and assuming we can get concentrations and dosages right, the current framework is suitable and this substance could be slapped down on top of it.

I am not being sarcastic, but I do not understand the reference to drug-free workplace policies. I hope that the consultant performing my operation or the pilot flying my plane is not using cannabis. There must be a distinction between something that is okay and something that, as a psychoactive substance, will impair judgment. We must be careful.

As I mentioned last week, it is currently the case that subscription medicines cannot be promoted to the public. I cannot understand why there would be different rules for any Schedule 1 drug even if it is moving to another Schedule. Perhaps someone can enlighten me on the situation.

I wish to address the dosing of medicines. Perhaps Ms Egan will explain something. Just because something has been around for a long time does not mean that it is all right. Aspirin comes from the willow - I hope I am correct in that - and people gave children baby aspirin until recently. That moved to age six and then 16 in my time. Just because something is a naturally occurring product does not mean that it is okay. For example, one will find out what happens if one eats enough foxglove. Codeine used to be given to breastfeeding mothers but that changed in the period between my second and third children being born. We are constantly building on evidence. Once a drug is authorised, the yellow card reporting system keeps updating our data with what we learn. All of this is done in the interest of public safety.

Perhaps one of the pharmacists will outline to the committee that, from a pharmacokinetics point of view, children are not small adults. Their metabolic processes and how they process drugs are different. If a child is one quarter my size, I cannot just quarter the dose. Perhaps someone will articulate the distinct pharmacokinetic difference between a child's metabolism and that of an adult.

Someone might enlighten me as to why there are references to the imperial system of measurement, for example, ounces. I do not understand why we would measure anything in ounces. I am very concerned about the lack of detail on dosing and concentration. As a pharmacist, I would find it difficult to dispense something if I did not know what it contained.

I will add something before I drive everyone completely mad. My understanding is that if this Bill goes to the Dáil and is voted through, any doctor would be able to prescribe cannabis for any patient, for any condition, anywhere in this country. That includes children and pregnant women, breast-feeding women and people on multiple medications. When we dispense we look at dosage, indications, side effects, contra-indications and interactions with other medicines, as well as people with reduced kidney and liver function, whether over time, because of age or because of other diseases. This is of great concern to me. When the HPRA authorises something, it rubber-stamps it as being okay. It is not okay to be ingesting cannabis, either by eating it, smoking it or taking it transdermally while also breast-feeding a neonate, as it is deposited in breast milk. The role of the HPRA is to protect public safety and help health care professionals to make decisions in the interests of the public.

The other issues include different registering and I do not see why the framework is any different. As a pharmacist, I have serious concerns about this Bill. I have other views on the decriminalisation and rescheduling of drugs but my main issue is with the use of the word “medicinal”. I am concerned that we would weaken our regulatory framework in any way and expose the public to adverse effects.

Deputy Bernard J. Durkan: I thank our guests for coming before the committee. I agree that all medicines have their danger levels and we are always advised that it is dangerous to overdose. However, I am most worried about health. As legislators, we have a very important role in the health and well-being of the community. If our health experts and our regulatory authorities are not happy and if they specify their reasons, we have to take it into account as our responsibilities are to the public at large. There has been more than one occasion on which particular procedures, which had the *imprimatur* of the authorities, were followed but wrongly so, as it later transpired, so we have a duty to ensure that whatever we authorise must be clear and we must have due regard to the expert information we get from the authorities whose job is to protect public health and well-being and the public good. There are potential legal liabilities and there is a possibility of the public making claims as a result of proceeding in a direction that is later proved to have been not in the public interest.

As a legislator, I have no hesitation in saying that I have to be bound by the medical and expert opinion given to us. At the moment, that indicates to me that this Bill, as proposed, is not satisfactory and not acceptable.

Mr. Eugene Lennon: I will ask my colleague, Ms Egan, to respond to the questions from Senator Burke and Deputy O’Connell on the work of the expert reference group. I confirm that, as Deputy O’Connell said, a system is in place for a licence to be issued for the prescription, possession and importation of cannabis-based treatments that contain THC if that application for a licence is endorsed by a consultant. As we said, a licence has been issued so a system is in place under current legislation.

The Deputy is also right that the legislation should refer to the Minister for Health because it concerns controlled drugs and medicinal products. On the question of penalties, a lot of offences are listed in this Bill and it removes cannabis from the Misuse of Drugs Act. However, while there are offences under this Bill, there are no penalties, no terms of imprisonment and no fines for any of those offences so there is no deterrent effect.

Ms Egan and our PSI colleagues will say a bit more about protecting children and women but these are issues which the expert reference group will look at. The expert group will focus initially on cannabis products being made available for the three conditions outlined by the Minister on 10 February but it is essential that it is not closed off from other conditions in the future. We have to provide guidelines for clinicians and pharmacists and information for patients so that we protect them. This is an unauthorised and unregulated product so we have to be cautious and prudent in setting up a scheme to make it available to members of the public. I agree that we should not see patients as consumers in a market system.

Ms Maria Egan: I will put the reason for the cannabis access programme into a bit of context. The evidence for the effectiveness of cannabis, which is being discussed in the public domain at the moment, in treating a number of conditions, including curing some serious medical conditions, is anecdotal and such an approach ignores the fact that the scientific data supporting them do not exist. As a result of these concerns it is very important that the access programme draws on the expertise of medical specialists who are responsible for the management of the

qualifying patient groups.

The HPRA's report concluded that robust scientific evidence on safety and effectiveness does not support the use of cannabis for clinical indications other than in very limited cases. Its review concluded that the cannabis access programme that is being established could include access to cannabis-based therapies for the treatment of patients with spasticity associated with MS, resistant to all standard therapies and interventions; intractable nausea and vomiting associated with chemotherapy despite the use of standard anti-emetic regimes; and severe refractory treatment-resistant epilepsy that has failed to respond to standard anti-convulsant medications. Under the access programme, patients with a diagnosis of any of these medical conditions will be under the care of a specialist consultant. We would all agree that the use of cannabis products in patients, especially children, with these very serious medical conditions should only be permitted under the direction and supervision of a specialist doctor. This is particularly important given that very few cannabis products are authorised as medicines. As my colleague has already said, they have not gone through the normal regulatory approval process for medicines which are, of course, designed to protect patients and ensure treatments are supported by good evidence of their effectiveness and safety. Through our work in setting up the cannabis access programme, we are engaging with clinicians, patients and pharmacists who will be central to the work of drawing up guidelines on the safe use of cannabis for those patients who will be prescribed these treatments through the access programme. A reference group has been established and is being independently chaired by Dr. Máirín Ryan, the director of health technology assessment at HIQA. She is also an assistant professor in pharmacoeconomics at Trinity College Dublin.

The aim of the group is to produce operational, clinical and practice guidelines for the access programme for medicinal cannabis in Ireland and to answer many of the operational questions that have been identified to date. This process is being informed by the HPRA report. The membership of that group draws on a broad range of representation from areas including oncology, palliative care, anaesthesiology and general practice. There are two patient representatives on the group. It includes adult and paediatric neurology, multiple sclerosis, psychiatry, pharmacy practice, the pharmacy regulator, health care ethics, a health technology assessor and the health products regulator and ourselves. The reference group began its work on 30 March and it is making progress on the drafting of the guidelines.

As well as having regard to the HPRA report, the group will also be guided by other international scientific evidence in developing these operational guidelines and implementing the programme. The focus of the work is to provide an operational framework as to how the scheme will work into the future. It needs to address clear questions such as the clinical criteria for patients accessing cannabis for medicinal purposes. It will include areas such as the use of any of these particular products in specific patient populations such as expectant mothers or whether there would be contra-indications for specific patient populations.

The cannabis access programme will be established but ultimately the decision on the appropriate course of treatment for any patient will be a matter for the clinician treating that patient and the Minister for Health would not have a role at that stage. Somebody asked how long it will take to finalise the guidelines. In announcing this programme, the Minister has requested that the group complete its work by the end of June this year so the access programme can be up and running as soon as possible. This work is well under way but it will take time to generate the answers to these fundamental and very important operational issues that need to be addressed. There is also the question of legislation that will be required to underpin the

programme.

Deputy O’Connell asked about other conditions that were not included in the HPRA report. Whereas the HPRA report did not conclude that certain other indications should be facilitated through the cannabis access programme, this does not mean patients cannot access such treatments if the consultant deems it appropriate. My colleague has already explained that the licence application process remains open to a consultant to apply for a named patient if assurance can be provided that the treatment will be monitored and overseen for that patient.

Mr. Niall Byrne: To follow up on the comments from the Department of Health officials, the position of the PSI is as set out in our statement. We very much support the work to develop the access programme and the members of staff of the PSI are involved with that work. We are very committed to ensuring our contribution to that work is very much focused, as I stated earlier in my statement, on the principle that the access scheme will work for patients accessing cannabis for medical use. From the point of view of supply being made through registered pharmacies by registered pharmacists, all of that would be on a safe, sustainable and proper footing. In exercising their professional judgment, pharmacists should do so in circumstances where there is as much clarity as possible in the decisions they make. A registered pharmacy is not just a shop and it is very important to say it is a particular type of service. It is governed by very clear regulatory requirements as to how the service operates. With regard to the dispensary aspect of a pharmacy in particular, it would operate under the personal supervision of a registered pharmacist, who is subject to accountability requirements of the PSI and a statutory code of conduct. Everything the pharmacist does happens within the regulated entity and the pharmacist exercises his or her professional judgment at all times. The PSI position is that this creates an appropriate scheme of regulation that is focused very clearly on the safety of the public. The code of conduct goes into these matters in great detail and the PSI’s role is to ensure those mechanisms work in practice.

In circumstances where we are looking at an access programme that represents a degree of change to existing circumstances, we have no reason to believe that pharmacists in general would not be disposed to following the PSI concept of engaging in and taking part in developments that are about trying to meet patient need in new and different kinds of ways. At all times this desire would be balanced with the need to maintain public safety. The balance is not easy or simple and the deliberations of the committee are very much highlighting that complexity. Our role is to try to be part of that balancing discussion while bringing our expertise and experience to bear on that.

In summary, we believe the access programme accords with those kinds of principles and the requirements of public safety. We are very keen to be involved in ensuring it delivers for patients who come to a pharmacy with a prescription so they can have the prescription dispensed in a safe and effective way.

Deputy Kate O’Connell: Could the witnesses refer to the fact that we are always learning and the yellow card system? There is a reference to the changes for codeine in the context of lactating mothers and the shifting of the age for aspirin. It is important to get the message out there that just because something grows in a field, it does not mean it is okay. I would like the witnesses to briefly outline how we constantly look at our data and just because something is a plant does not mean it is fine.

Vice Chairman: We should not put them on the spot. If they can comment, they will.

Ms Maria Egan: Any new product that has a medicinal use must go through very rigorous clinical trials and they must be approved at the various stages to prove the benefits of the product outweigh any risks to the patient. As Deputy O'Connell has stated, even when a product receives approval from the medicines regulator, it does not mean the monitoring stops there. It is continuously monitored in the wider population. The HPRA oversees a pharmacovigilance system for all medicinal products. Some products are particularly high risk. It is the responsibility of the pharmacist to ensure patients are made aware of any side effects they may experience and what to do if they experience those side effects. Patients are also encouraged to report their experiences to their doctor or the pharmacist. This information is constantly collated and reviewed. At national and European levels, medicines are constantly reviewed to determine whether they remain safe for use and to ensure their benefits continue to outweigh the risks. We are constantly learning, particularly so in terms of products such as the one we are discussing, because they are different. While they remain different they need to be monitored by the experts to ensure if they are to be used they are safe to use.

Dr. Cora Nestor: The professional role of the pharmacist is to advise patients on the correct use of a product. In terms of the supply of products, a pharmacist must be capable of calculating the dose of a product, advising the patient on how to use it and on any influence it might have on other medicines they are taking and on other issues such as interactions with food and so on. In regard to vigilance and the access programme, my understanding is that the HPRA's recommendation is that data on patients going through the programme should be collated. There would be an opportunity arising from the access programme to collect data and to continuously learn in regard to the safety profile which the HPRA says has not been established.

Vice Chairman: We, too, are constantly learning.

Deputy Billy Kelleher: I welcome the witnesses. Some of the technical issues have been covered by other Deputies and Senators. My questions relate to the Bill and the Health Products Regulatory Authority's recommendation on the access programme.

When the Department of Health was asked for its views on the Bill did the Chief Medical Officer have any input in that regard? Did that office express any particular views on this Bill as proposed and on the broader issue of the HPRA's recommendations on the access programme or were its views sought?

With regard to the European Medicines Agency and its recommendations, does it follow suit that if a medicine is recommended by the European Medicines Agency the Health Products Regulatory Authority is obliged to licence use of the product in this State or does the European Medicines Agency supersede the Health Products Regulatory Authority? What is the relationship between the two agencies in terms of authorisation for the use of any drug or medicine?

Mr. Lennon mentioned in his opening remarks on the Bill that the Department is of the view that it is not necessary and is not in the public interest. Is the Bill not in public interest because it proposes to establish parallel regulatory authorities or because of concern about health implications? Perhaps Mr. Lennon would elaborate on that issue.

On the access programme, is there sufficient architecture in place in terms of regulation to allow for the dissemination of cannabis for medicinal purposes through the pharmacies or is additional regulation or legislation required to fulfil the HPRA access programme recommendations?

The report states that there is evidence to suggest that this product could be beneficial in the treatment of pain, although some of that evidence is not supported by broad clinical trials. Does the HPRA continually analyse the clinical evidence produced on a regular basis in regard to all products and medicines and does it have the capacity to monitor the international evidence in that regard, be it in favour or otherwise of a health product currently being authorised in the State through an access programme or the pharmacies?

Deputy Richard Boyd Barrett: The term “expertise” has been used a lot. What specific experience, knowledge or expertise do the Department of Health officials or the PSI representatives have in the area of medicinal cannabis, research in that area or clinical expertise in the specific area of medicinal cannabis products? My understanding - I am happy to be contradicted - is that they have no such knowledge, expertise or experience. Also, what specific experience, knowledge or expertise does the HPRA have in the area of medicinal cannabis products because it has cited none in its report and to my knowledge it has none. Again, I am happy to be contradicted.

Why do the Department of Health recommendations run counter to the evidence provided by people who have extensive knowledge and expertise in the area of medicinal cannabis, namely, Professor Mike Barnes, consultant neurologist, professor of neurological rehabilitation and author of the authoritative report on medicinal cannabis for the UK Parliament? According to Professor Barnes the evidence is strongest for the efficacy of medicinal cannabis in the area of pain whereas the so-called access programme being proposed excludes this cohort. Professor Mike Barnes and Professor David Finn, who has spent 16 years researching the area of medicinal cannabis, say that this is the area where the evidence is strongest yet this is the area excluded by the access programme. I would like an explanation for how that could be the case.

Could the witnesses explain what they will do for the 800,000 people in Ireland who suffer from chronic pain, of whom 40% do not get relief from existing authorised pain killers, according to Professor David Finn? Do the witnesses believe it is acceptable that cohort, a very significant number of people who get no relief from existing authorised pain killers, should continue to be criminalised for using medicinal cannabis products? If we adopt the witnesses’ recommendations, that will be the case. They will be criminals. They are currently criminals and they will stay criminals. Do the witnesses think that is acceptable?

How would the witnesses respond to a survey of GPs in this country which showed that 58.6% of GPs, the people who do not regulate and do not sell medicine but who actually prescribe it and are medical professionals, favour the legalisation of cannabis for medicinal use? An even higher proportion of GPs with advanced addiction specialist training level 2 agreed or agreed strongly that cannabis should be decriminalised, bringing the percentage to 60%. Do the Department of Health, the PSI and the HPRA think they know better than GPs, particularly GPs who specialise in the area of addiction? I put it to them that they do not. I find it incomprehensible that they are second-guessing them.

Could the witnesses tell us what they have done to look into the five other EU countries, subject to the same EU directives in terms of the regulation of medicines, which have adopted legislation similar to that proposed by Deputy Gino Kenny allowing for wide access to medicinal cannabis based on the prescription of certification of GPs and not requiring consultants? Could they confirm that consultants have no legal status in Irish law?

Could they tell us how many people die from products that are authorised pain killers or other drugs authorised by the HPRA, specifically benzodiazepines and opiates, every year in

Ireland? That would be useful. Following that, could they then tell us how many people are known to have died from medicinal cannabis products anywhere, in Ireland or elsewhere? We have testimony from Professors Mike Barnes and David Finn that the side effects of medicinal cannabis products, and they acknowledge there were some, were moderate. Is that how they would describe the potential side effects or adverse consequences of the misuse of drugs that are already authorised, particularly opiates and benzodiazepines? How do they square that circle, or inconsistency, that we already regulate, authorise and sell drugs that are toxic, that kill people and that are regularly misused but that we propose to have a higher level of restriction on a medicinal product which although it may have some side effects, there is no evidence they are anywhere as serious as the effects of drugs already authorised and sold in chemists up and down the country on the basis of a GP's prescription?

Some red herrings have been thrown into this debate. Could the Department of Health confirm that we have stated repeatedly in both public and private meetings, in the Dáil and elsewhere, that we are more than willing to amend this Bill in many of the areas on which concern has been raised? For example, we would be quite happy - in fact, we agree - that the Minister of Health is the Minister who should be referred to. The reason we referred to the Minister for Justice was because of the current criminalisation. All we want with this Bill is one that will allow access to people who could medically benefit from cannabis products on the recommendation, or prescription if people want to change it to that, of a medical professional and that it would be regulated. There would be continuous research in the area on an ongoing basis to establish the efficacy, effects and consequences of medicinal cannabis use. That is the centrepiece of this Bill. We are quite willing to consider amendments on everything else which has been raised, whether on penalties or on where in the Schedule it should go, and which are incidental to the central thrust of this Bill which is one to allow medical professionals, not just consultants, but GPs or other medical professionals to be able to prescribe or recommend medical cannabis to any patient who would benefit from it. That is the core of this Bill. Does the Department of Health not know that we are happy to accept amendments? Could it explain why that is problematic?

Deputy Gino Kenny: I am trying to be objective but when I heard the HPRRA report was out, a small part of me wondered if maybe it was progress and that it might be a small step towards what we set out seven or eight months ago and that people who are suffering unnecessarily could gain access to medicinal cannabis. I thought there could be a small bit of small progress but then I read the HPRRA report and what exactly the cannabis access programme is. The cannabis access programme being approved by the Government is not progress; it is regressive. It stipulates three conditions but leaves out chronic pain. This is absolutely bizarre. The Barnes report, which is a very well respected report, states that chronic pain is the No. 1 issue where medical cannabis can be very effective. That is across the board. The three conditions named in the programme are spasticity, intractable epilepsy and the side-effects of chemotherapy. What drugs will be administered for those treatments? I understand the drugs that will be administered for those three treatments will be Sativex, Epidiolex and probably one or two other pharmaceutical-grade cannabis-based products. There is a family in the North of Ireland whose daughter has Dravet syndrome and who have been turned down for Epidiolex. If the cannabis access programme stipulates that it can be administered only in pharmaceutical-grade products, it is going nowhere. We set out seven or eight months ago that people should have access to the full plant extract.

There have been two applications for licences. One was successful while the other was not, which is good for one family and very bad for the other. The officials say that this is the kind of

programme which the Minister can admit. What do they say to hundreds of people who want to access that licence system? It is completely unsustainable. The Minister will have 400 or 500 applications in respect of the system. I would like the officials to comment on that. I asked Mike Barnes last week what he thought of our compassionate access scheme for a licence and he said it is completely unworkable. That is why we want our Bill to go through, to give the many who could benefit from it access to medicinal cannabis on the full plant extract.

As Deputy Boyd Barrett said, there is duplication. If the HPRA can do what we propose in the Bill for a cannabis regulation authority, so be it. I do not want duplication or another quango in this country. If that can do exactly what the cannabis regulation authority and the cannabis research institute can do, I am happy to say let us get on with the job. If it cannot, we have a big problem and the regulation authority and the research institute have to be put in place. Otherwise, the Bill deteriorates.

I would like Mr. Lennon to answer some questions on points I have heard in the past couple of months about medicinal cannabis. I wish Deputy O'Connell was still here to answer too. She stated that one can overdose on CBD oil but one cannot. She also said there will be blood on the hands of the State if this legislation goes through. That is quite an extraordinary statement. She then made parallels between thalidomide and cannabis. That is another extraordinary statement.

Deputy Bernard J. Durkan: She will be back.

Deputy Gino Kenny: I hope she answers these questions.

Vice Chairman: The purpose of this committee is to hear the evidence and question the people who are here.

Deputy Richard Boyd Barrett: We want the Department of Health's comment on those allegations.

Vice Chairman: I fully understand that but there will not be any back and forth between members. That can take place outside. I would like the members to stick with the job on hand.

Deputy Gino Kenny: I would like the Department of Health to state whether one can overdose on CBD and answer all the other questions I posed.

There are ten countries in the European Union that have programmes similar to the one the Department is trying to advocate. It is a regressive programme. It is not even restrictive. Why is the bar so high that it means virtually nothing to anybody? In terms of the overall picture and regardless of whether people in this room agree, there are people in this country using cannabis to treat their conditions and they are criminalised. That is immoral. They should have the choice to go to their GP or consultant to get medicine that may not be recognised by the HPRA. Under the licence system, one family has gained legal access to it for their child. Why should other families not gain access to it? The system is not in place because it needs legislative change. That is why we have put this Bill forward and I think we will be successful. The onus is on everybody in this room, like it or not, to answer people who say that they will be medically discriminated against because they are not part of that access programme. I would like to see anyone here, member or not, sit in a room with a person who suffers chronic pain and will now suffer again because they are left out, and say that to their face.

Mr. Eugene Lennon: I will start off but there is a long list of questions and I am sure that

my colleagues will come in on some of them. Deputy Kelleher asked why I said the Bill is not in the public interest and wanted the views of the Chief Medical Officer. It is his view also that the Bill is not in the public interest. He believes there is an established system of regulation for medicines and controlled drugs in place already and that we are setting up a parallel system for one substance, cannabis, and undermining the systems that exist for medicines and controlled drugs. There is also the concern about the Misuse of Drugs Act 1977, and I take on board Deputy Boyd Barrett's point that was not the intention. Removing reference to cannabis from that Act, taken with references to recreational use of cannabis, to encouraging employers to review their drug free workplace policies and no penalties for the offences in this Bill gives a sense that it is heading towards decriminalisation of recreational use of cannabis. That may be because large parts of it were taken from former Deputy Luke 'Ming' Flanagan's previous Bill, which went much further in the direction of recreational cannabis.

The Department and the Chief Medical Officer are concerned that any doctor could issue a certificate for any condition under this Bill because we are talking about a substance that is not a medicine and has not gone through the normal regulatory procedures and about very serious illnesses.

Deputy Richard Boyd Barrett: Does the Department not trust doctors to prescribe?

Mr. Eugene Lennon: We do trust doctors but we are concerned about unauthorised products being prescribed for very serious medical conditions.

Deputy Richard Boyd Barrett: That is not what the Bill is proposing. That is factually incorrect.

Mr. Eugene Lennon: That is what the Bill allows.

Deputy Richard Boyd Barrett: It does not.

Mr. Eugene Lennon: It does.

Deputy Richard Boyd Barrett: It does not.

Mr. Eugene Lennon: In fact, it does.

Deputy Richard Boyd Barrett: It does not. It says a doctor prescribes authorised products.

Mr. Eugene Lennon: They are not authorised medicines.

Deputy Richard Boyd Barrett: The Bill would allow them to be authorised. What Mr. Lennon says is complete nonsense.

Mr. Eugene Lennon: It is setting up a parallel system. That is not the way to authorise medicines.

Deputy Richard Boyd Barrett: That is what the Department says and we say the HPRA can do it. We are saying that doctors would prescribe medicines authorised by a regulatory body. The latter would be either the HPRA or a cannabis regulatory authority, we do not care which. That is what it says and Mr. Lennon knows that damn well.

Mr. Eugene Lennon: If cannabis were capable of being authorised like a medicine, the companies that are making medicinal cannabis - there are many which do and which make a

lot of money from it - can produce the clinical evidence and apply through the authorised-----

Deputy Richard Boyd Barrett: All the people selling the stuff that is out there now are making a lot of money out of it.

Mr. Eugene Lennon: They can apply through the normal authorisation procedures and see if those products get authorised as medicines. That system is open to them.

Deputy Richard Boyd Barrett: Mr. Lennon is saying that the Department does not trust GPs to prescribe a product that we are proposing-----

Mr. Eugene Lennon: I think the Deputy is the one bringing the word “trust” into this issue.

Deputy Richard Boyd Barrett: Mr. Lennon expressed concern about GPs.

Mr. Eugene Lennon: Yes.

Deputy Richard Boyd Barrett: What is the concern? Does Mr. Lennon think general practitioners are going to prescribe a dangerous product?

Mr. Eugene Lennon: We believe that where products are not authorised, this is not the best way to proceed. If I may bring one item to the attention of the committee, the Royal College of Physicians of Ireland issued a statement on 15 March. It was from the consultant neurologists who treat adult and paediatric epilepsy. On prescribing cannabis, they stated, “Currently the main barrier to the prescribing of cannabis derivatives for epilepsy is the lack of clinical evidence of its long-term efficacy, as well as lack of data on long-term side effects.” That is why cannabis is not being prescribed at the moment.

Deputy Richard Boyd Barrett: For epilepsy.

Mr. Eugene Lennon: They are the specialists and that was one of the most frequently mentioned illnesses in our discussions of cannabis.

Deputy Richard Boyd Barrett: Mr. Lennon did not answer the question about pain.

Mr. Eugene Lennon: The Deputies and Senators have a long list of questions.

Vice Chairman: There is a long list of questions that have been asked. Can we try to get through them as best we can? If anything is missed, any member wishing to come back in will have an opportunity later.

Mr. Eugene Lennon: Deputy Kelleher mentioned the architecture of regulation in parallel with the work of the expert reference group. The Department is also considering secondary legislation under the Misuse of Drugs Act that could underpin the access programme. That will take a number of months.

Deputy Billy Kelleher: Will that be a statutory instrument or a ministerial order?

Mr. Eugene Lennon: Statutory instruments. We reckon we will need at least three in respect of the access programme.

Returning to some of the other points that were made, my colleague will deal with the question about the European Medicines Agency, EMA. Outside of the access programme, it will still be open to people to apply for a licence where their consultant endorses the treatment

and feels it appropriate. If somebody has another condition outside of the three that are in the access programme initially, it is open for a consultant to apply for a licence for treatment with cannabis. It was suggested that we would be overwhelmed with licence applications. That will obviously not be the case. We have not had very many to date. The access programme itself will not require a licence as that is not how it is being set up. Patients will be on a register for treatment under it.

As reference has been made to the Barnes report, it is worth noting that the Minister initiated his review of policy on medicinal cannabis last November and now we are working on the guidelines for an access programme. Professor Barnes published his report in the UK well over a year ago and there is no progress there. There is no access programme or any change in anything. We are making a lot of progress very quickly in Ireland, partly because the HPRA programme set out how something could work in a practical health care setting.

Reference has been made to other European countries. The numbers receiving cannabis are not as high as one might think. Our understanding is that in the Netherlands, a country with a population of 16 million people where there has been access to cannabis for medical purposes for over a decade, we are talking about 2,000 patients in total. The idea that 40% of 800,000 Irish patients will end up on cannabis is not realistic. The numbers in other European countries are quite small. In some of them, the access programmes are only getting going at the moment. Denmark's population is greater than Ireland's by about 1 million. They reckon that after four years they might have up to 1,500 people on their access programme. The HPRA said that there are three countries in Europe with more liberal regimes and about eight countries with access programmes. Ireland is joining those eight countries. The majority of EU countries still do not even have an access programme for cannabis.

There is a lot of talk about the risk from benzodiazepines and other products. That does not pertain to the substance of this Bill. We have set out what we believe are issues around this Bill. The benzodiazepine question is a different issue not covered by the proposed legislation. Some of the issues in that regard have to do with the illegal sale of benzos rather than those prescribed by doctors and dispensed by pharmacists. Yes, benzos cause problems for people and they are misused. However, if used appropriately, they are of benefit to patients and there is a positive benefit-risk ratio when those products are used appropriately. That is a different argument from what is proposed here in respect of cannabis.

Vice Chairman: If I may interrupt for a moment, I am obliged by another commitment to absent myself from the chair for a short time. I nominate Senator Colm Burke to take my place if there are no objections. Is that agreed? Agreed.

Senator Colm Burke took the Chair.

Mr. Eugene Lennon: On the products that might be available under the access programme, the HPRA report recommends that authorised medicines are considered in the first place. That would include Sativex. Epidiolex is currently undergoing clinical trials. Other cannabis products can be allowed under the access programme. That is one of the issues the reference group is examining but it is going to take a few months to come to conclusions. Cannabis products other than the authorised medicines are certainly not ruled out. A consultant would have to make the relevant recommendation and approve the treatment.

Ms Maria Egan: On Deputy Boyd Barrett's point about what he sees as a lack of expertise specific to cannabis use, the experts who have been asked to contribute to the production of

guidance for prescribers, patients and pharmacists have very specific expertise in their specialist areas, which span a breadth of clinical indications. That group will be informing itself on the use of cannabis for the production of those guidelines. It will be a learning exercise for the experts.

Deputy Richard Boyd Barrett: Experts who know nothing about cannabis.

Mr. Niall Byrne: If I could make a short contribution following on from my colleague from the Department, the expertise of PSI is in respect of its regulatory remit. That remit covers the regulation of retail pharmacy businesses and of pharmacists as registered professionals. We do not claim to be experts in areas beyond that remit. In respect of giving a view that would be helpful to the committee, we are obviously not here to comment on actions by other professionals. However, the role of pharmacists is not simply to stand in the dispensary and hand over whatever a prescription specifies when it is presented. Pharmacists are expected and indeed required by the regulatory framework to use their professional skills, competencies and specialist knowledge about medicines to ensure that a patient only receives medicine that is going to be safe and efficacious in respect of his or her specific needs. Our code of practice is a statutory code of conduct against which pharmacists are held accountable to the highest level. It states that there may be circumstances in which the judgment of the pharmacist might conflict with the stated requirements of the patient. That is the exercise of professional judgment. These are not simple matters. Our system of control for medicines to ensure the safety of patients and the public does involve various checks and balances.

Deputy Boyd Barrett made a point about GPs issuing prescriptions. I do not have a view on the manner in which GPs issue prescriptions. That is entirely a matter for GPs. Our system does not work in such a way that a prescription leads to the supply of specified medicines. The pharmacist plays an important role and exercises his or her judgment on what is or is not dispensed in terms of a prescription. Pharmacists commonly engage with GPs and other medical professions on what is specified on prescriptions and whether it is intended and efficacious for the patient. There can be a lot of dialogue between the relevant professions. It is not simply a case of prescription equals supply. That is not the way the system works.

We are all very concerned about the well-being of people who find themselves in circumstances where they need access to medicines. They may have conditions that are quite intractable and resistant to conventional forms of treatment. I hope I noted Deputy Boyd Barrett's words correctly that he uttered in the heat of the moment. It is important to note the following. It is not the case that we, as an Irish society, sell drugs that kill people. That is not what happens. No pharmacy knowingly sells drugs that can kill people. Medicines have inherent risks. Many medicines are toxic and have toxic effects, as we all know. It is important that the Deputy's statement does not simply sit on the record. He possibly did not intend to make the suggestion. In practice, we all seek to minimise and balance the risks of medicines of all kinds with the potential benefits. As the committee reported in its report on medicinal cannabinoids that it published last January, there are risks and potential benefits. The report called for careful cognisance of the attendant risks and made the following recommendation. The foreword stated: "It is the Committee's view that Ireland should pursue a balanced course of action in considering the merits of authorising the use of medicinal cannabinoids". The Pharmaceutical Society of Ireland, as the regulator of pharmacies, supports that position because we feel it is in the public's interest. The foreword contained a public interest statement. My colleague, Dr. Nestor, will make a few helpful points.

Dr. Cora Nestor: As mentioned previously, the qualification for pharmacists is laid down in

statute under EU legislation. About 10% of the qualification refers to drugs from natural origin, which is an area called pharmacognosy and phytochemistry. All pharmacists would, as part of their training, study this area that includes medicinal and non-medicinal cannabis. A pharmacy qualification ensures there is expertise and knowledge of the area.

Deputy Richard Boyd Barrett: It is unfortunate that many of my questions have not been answered. I asked the following direct question. What specific expertise and knowledge does the Department of Health, the PSI or the HPRA have in the area of cannabis? I do not doubt that the organisations employ experts in their fields. I want to know who we have taken advice from. Are they experts who know nothing or a lot about cannabis? I suggest to Mr. Lennon that we would be better off taking advice from experts who know something or a lot about cannabis. I wish to advise the committee that I shall formally write to the clerk of the committee requesting that the committee arranges an engagement with Professor Mike Barnes. It is the least that we can do if we want to have a comprehensive view of this matter. I say to Mr. Lennon that the fact the British political system has not responded to the recommendations made by Professor Barnes is irrelevant. Will our attitude to medicinal cannabis be informed by somebody as expert and knowledgeable as Professor Barnes or by people who have no knowledge whatsoever about cannabis? Professor David Finn is professor of pharmacology and has studied cannabis for 16 years. He explained in great detail how there was strong evidence at every level to support the efficacy of cannabis-based products to relieve pain, as did Professor Barnes.

Professor Finn told this committee that there was a significant unmet need. I asked the witnesses what they would do to solve the unmet need. Mr. Lennon told me how many or how few thousand people availed of access programme in other countries but he did not answer my question. What will the Department's access programme do for the unmet need whereby people do not get pain relief from existing drugs? I put it to him that the programme will leave them out in the cold and label them criminals if they attempt to access the product. I asked the witnesses whether they thought it acceptable that such people were criticised and that the access programme left them out in the cold. I put it to them that it is unacceptable. I further asked them to respond to the fact that the majority of GPs in this country, and a higher proportion of GPs with specific knowledge in the area of addiction, favour the decriminalising of cannabis for medicinal purposes. Why have the witnesses not taken the lead from them?

Deputy Jonathan O'Brien: We have discussed this matter at Second Stage. As Deputy Gino Kenny will know, I have expressed serious reservations about some of what is contained in the Bill. Medicinal cannabis is an emotive issue for many people. First, I do not agree with the establishment of a cannabis regulatory authority. Second, I do not agree with the establishment of a research group into just cannabis. I support the access programme but would like it extended to beyond the list being considered. I understand that the access programme will be reviewed after five years and there is a possibility it will be extended at that time. I ask the officials to clarify the matter.

There are two arguments about cannabis. First is the provision of cannabis for medicinal purposes, which I have no issue with. Second, there is a difference of opinion on how medicinal cannabis can be provided. I believe existing bodies should consider the products, benefits and potential side effects.

I take on board what has been said by Deputy Boyd Barrett. He wants us to insist that whoever considers all of these matters has an expert knowledge of cannabis. If the Department does not have such expertise then it must bring in experts, as part of the deliberations.

Deputy Richard Boyd Barrett: We do that.

Deputy Jonathan O'Brien: I am saying that the Department needs to do so. Is this Bill the quickest way to achieve medicinal cannabis? I do not believe it is. I think the access programme will be up and running.

Deputy Gino Kenny: Does that mean Deputy O'Brien is not supporting the Bill?

Deputy Jonathan O'Brien: In fairness, I supported it on Second Stage. We are now at the pre-committee scrutiny of it. I have always said that if it goes to Committee Stage, we will table a number of amendments and, based on those, we will then make a decision on whether we support the Bill. It would depend on whether those amendments are passed or rejected. We would not support the Bill in its current form.

Acting Chairman (Senator Colm Burke): We want to confine what is said to questions to the panel.

Deputy Jonathan O'Brien: We have two parallel processes now. We have this Bill, which is going through the Oireachtas, and we have the access programme. What people outside of this room want to know is which is going to achieve the objective more quickly. I do not know whether the Department is going to support this or is going to leave it to go to committee and try to amend it. I do not have the answer to that. Does Mr. Lennon know what the Department is doing on this Bill?

Acting Chairman (Senator Colm Burke): I will call Deputy Kate O'Connell and then we can deal with those issues. Mr. Lennon dealt previously with some of the issues raised by Deputy O'Brien.

Deputy Kate O'Connell: I want to bring up a point about experts and people who would have expertise in the area of cannabis. The argument that has been put forward would, to my mind, suggest that any novel drug would have such issues. Nobody has expertise because it did not exist before. Consider this for any new product, for example, in yesterday's great announcement with Orkambi. There was nobody in the Department who knew anything about Orkambi until the data came through from the manufacturer, because the data did not exist. I believe the argument being put forward about the lack of experts in the field is a null argument.

The extensive undergraduate programme and training for pharmacists gives us the capacity, through our knowledge of pharmacology, pharmacokinetics and all of that, to apply those professionally acquired skills to make reasoned decisions in the interest of public safety once a new drug comes on to the market. A pharmacist does not just stop learning the day he or she gets a certificate, but instead he or she constantly learns and updates knowledge. There are quite cumbersome processes in place for that level of expertise to be maintained, all in the interest of public health. I do not think it is fair to suggest that because something is new, some lad has to go off and do a degree in Orkambi or whatever. We have the skill set, as does the technical end of the pharmacology sector.

I refer to an expert, a professor of pharmacology, who was before the committee. Perhaps I am wrong but I do not believe that scientists, as in pharmacologists, as distinct from pharmacists, have any professional regulatory ethical body. Maybe I am wrong about that. Nonetheless, a pharmacologist is a scientist in a laboratory environment with no interaction with actual people or patients. There is a distinct difference between a pharmacologist and pharmacist. Pharmacologists are not mentioned in any of the regulations about misuse of drugs.

Reference was made to the fact the majority of GPs in this country are up for this. I have seen no study which shows that to be the case, and it is regrettable that the Chairman, Deputy Michael Harty, is not here. If that evidence has been stated here, it is important that members of the committee would get that study and consider it.

Acting Chairman (Senator Colm Burke): I ask Deputies to ask questions to the witnesses here.

Deputy Kate O'Connell: I asked if the PSI could refer to the pharmacologist-pharmacist argument and the matter of GPs. There are questions there. Deputy Jonathan O'Brien spoke about there being two processes, and I agree with him on that. This is about the two processes. My concern is on medicinal matters. How can we help people? What is the best way to expedite this process for people who require treatment? I firmly believe we have to maintain the regulatory framework we have in this country to protect public health.

Deputy Bernard J. Durkan: Notwithstanding that Mr. Lennon's professional competence has been questioned, does a particular medicine have the same effect on all patients and users? Could I not say I believe a particular drug is the ideal thing for a particular problem? Is there a difference in the way it might affect other people, given their different metabolism? Does Mr. Lennon have the professional competence to answer that question? What is the difference between cannabis and medicinal cannabis? Will he shed some light as to what it might be? I do not know what cannabis does. I have not had any experience with it. I do not even know what it looks like. Is there a difference between the one a person can grow in a pot, which I have heard about, and medicinal cannabis? We were given information previously to the effect that cannabis-based drugs are available and authorised under existing legislation, and require prescriptions or whatever the case may be. Is that true? Are they available?

Who has responsibility for the health and safety of the population of the country in the event of there being a readily available product that some people question and others do not from the point of view of medicinal benefit? Is cannabis the only alternative? I recognise that it has use in situations of severe pain, as I have mentioned previously, but is it true that cannabis is not the only alternative? Does it have to be cannabis only? Are there alternatives other than cannabis, whether medicinal or non-medicinal cannabis? I know Mr. Lennon is going to tell me about types of cannabis in a second. Are the alternatives successful or not, and is Mr. Lennon professionally qualified to answer that question?

Acting Chairman (Senator Colm Burke): I know there are a whole range of questions and some were asked already, but Mr. Lennon might briefly go through them. I have one question. What is the current position for a GP who decides to apply for or go through the process to receive professional indemnity insurance? Will existing professional indemnity insurance cover this or is that an issue that needs to be looked at as well?

Mr. Eugene Lennon: I have a general point on the issue of expertise. The people on the expert reference group are medical consultants in a range of fields that Ms Maria Egan set out earlier, including multiple sclerosis, epilepsy, oncology, pain etc. To say that these people have no expertise is unfair-----

Deputy Richard Boyd Barrett: I did not say that.

Mr. Eugene Lennon: -----though that was implied-----

Deputy Richard Boyd Barrett: It was not implied.

Acting Chairman (Senator Colm Burke): The Deputy was given a chance to ask a question.

Deputy Richard Boyd Barrett: He is misrepresenting what was said. It is really annoying.

Acting Chairman (Senator Colm Burke): In fairness, Deputy, he is replying to the questions.

Deputy Richard Boyd Barrett: It was not implied. I asked if they had expertise in the specific areas.

Deputy Bernard J. Durkan: The Acting Chairman was here.

Mr. Eugene Lennon: I am trying to answer that question. These consultants deal with patients and families every day. I have spoken to a number of them about the cannabis and THC issue and they tell me the scientific papers they have read about it. The same applies for any other new treatment coming along. They inform and educate themselves about new treatments and they are anxious to find them. If new treatments are available, they will upskill for those treatments. As I noted from the earlier statement, if they are unwilling to prescribe currently, it is generally because they are not satisfied with the level of clinical evidence that is available. That is what I have to say about expertise.

The access programme is progressing and people are working on guidelines. They are also looking at guidelines that exist in other countries. I know in the past week that the people in the expert group drawing up the guidelines for clinicians and prescribers, as well as information for patients, have been looking at information from Australia, the United States, Canada and other places. They have considered the type of guidelines that would help inform the various health professionals when it comes to prescribing cannabis and dispensing and supplying cannabis-based treatments for people. We are looking at what happens abroad. I know that when the HPRA did its report, it contacted medicines agencies and experts in other countries as part of its work.

Reference was made to a survey of GPs and I understand there was a 15% response rate to the survey. The survey was probably taken before this Bill was published and before the access programme or the publication of the HPRA report. The question may not be directly relevant. Of the minority of GPs that responded, the numbers given by Deputy Boyd Barrett are accurate regarding those who said that medicinal cannabis should be available in some form. In a sense, it is. There is the option of the licence when endorsed by a consultant. There will be the option of the access programme for the three conditions initially and possibly for other conditions in future. In parallel with the access programme, the licensing option will still exist. If a consultant has a particular patient where nothing is working, based on the reading of scientific papers the consultant may believe that cannabis-based treatment may be the right option. The consultant can then apply to the Minister.

Deputy Jonathan O'Brien: That is outside the three conditions.

Mr. Eugene Lennon: Yes. We have informed both health professionals and patients that this continues to be the case when they contact us. The reluctance comes from the fact that many consultants are not happy with the state of the clinical evidence.

Deputy Durkan asked the difference between medicinal cannabis and cannabis, which is

interesting. Sometimes the terminology can be used to distinguish between street cannabis and cannabis that people wish to take for medical purposes. Sometimes the cannabis is the same in the sense that it is the same dried cannabis material that is grown. It is the whole-plant cannabis that Deputy Gino Kenny referred to. It is available in certain countries, such as Canada or the Netherlands, and one can get a tub of leaf cannabis. It is the same material that people might smoke illegally in a recreational way. In other cases, what people refer to as medicinal cannabis has been processed further into an oil, powder or some other form. It is the same constituent material and there are different strengths to cannabis, as there are with recreational or illegal cannabis. There are different strengths of THC and CBD when cannabis is used for medicinal purposes. It is the same material and the purpose can be different. Sometimes the form is also different. There is an cannabis product, Sativex, which is authorised for treatment of multiple sclerosis and there are synthetic cannabinoids that are authorised, including Nabilone. There is a pure CBD product going through clinical trials now that is called Epidiolex. It is at phase 3 trials and some of the health professionals working in the epilepsy are quite interested in seeing the results of the next stage of those trials.

There is the question of indemnity. We checked with the State Claims Agency and it indicated that if a consultant is prescribing cannabis, either under licence from the Minister or part of the access programme, he or she will be covered by the clinical indemnity scheme in those cases. I suppose in the way it is operating currently, the treatment must be endorsed by a consultant either through licence or the access programme.

Ms Maria Egan: There was a question from Deputy Durkan about whether one medicine would have the same effect on anyone that it was given to. That is not the case. Once a medicine is authorised, it is done for specific patient populations and contraindicated in many cases as well. The doses will be different for separate patients and the same dose would not apply to an adult as against a child or even with a patient with reduced kidney or liver function. Doses must be adjusted. That point is particularly relevant when one thinks about the use of cannabis. The endocannabinoid system, which is the system of cannabinoids in the body, was really only discovered in the late 1990s. Professor Finn probably went into much detail about how little is known about that system and how we do not know how cannabis interacts with that system, produces its effects and may interfere with other medicines that a patient may be taking. It could result in an enhanced effect of some other prescribed medicines or reduce the intended effect. Those outcomes will potentially be negative for a patient. The issue must be very carefully thought through before any decision is made about prescribing any medicine to a patient. It is done on a very individual basis.

Mr. Niall Byrne: I have a brief point on indemnity. Retail pharmacy businesses are governed by their own indemnity insurance and they are required to have that. As and when the access programme is introduced, there would need to be discussions between pharmacy operators and insurers as to whether there might be indemnity issues arising.

Acting Chairman (Senator Colm Burke): That discussion has not yet taken place.

Mr. Niall Byrne: It has not taken place because we will need to await the detail of what the access programme consists of and the checks, balances and requirements are around the access programme. This relates to commercial insurance companies as opposed to the State Claims Agency, as might operate in the public system.

Acting Chairman (Senator Colm Burke): What is the position regarding GPs? Is there any clarification on that?

Mr. Eugene Lennon: It is primarily intended that the treatment would be consultant-initiated. The GPs may have to check with their insurer.

Acting Chairman (Senator Colm Burke): I presume GPs would supervise this.

Mr. Eugene Lennon: Yes, GPs would be supervising this. These issues must be checked further. Some GPs have made individual contact with their medical protection society. It seems that if one is operating within a system where the overall treatment has been improved by a consultant, there is a level of protection. Where GPs will be working under guidelines approved by the expert reference group established as part of the cannabis access programme, it will provide a certain amount of protection. These are among the issues that are being discussed as part of the establishment of the operational basis for the access programme. The issue was discussed with health professionals in the very recent past as part of that work.

Deputy Richard Boyd Barrett: I would like some of my questions answered that have not yet been addressed.

Acting Chairman (Senator Colm Burke): In fairness-----

Deputy Richard Boyd Barrett: Mr. Lennon did not answer them.

Acting Chairman (Senator Colm Burke): The witness went through each of the questions asked.

Deputy Richard Boyd Barrett: No, he has not.

Acting Chairman (Senator Colm Burke): I do not think he can give any more information.

Deputy Richard Boyd Barrett: I asked him a direct question about whether he believed it was acceptable that people with chronic pain who took medicinal cannabis products should continue to be criminalised and whether that was the effect of the access programme that he was proposing. It is a simple question and is in line with the-----

Acting Chairman (Senator Colm Burke): An expert group is examining the process for setting up the access programme. That is a matter-----

Deputy Richard Boyd Barrett: According to testimony given to the committee, chronic pain is being left out, the Department does not want to support the Bill and, therefore-----

Acting Chairman (Senator Colm Burke): Does the Deputy accept that a process is under way?

Deputy Richard Boyd Barrett: No, I do not accept there is any process at all for people with chronic pain.

Acting Chairman (Senator Colm Burke): No. The expert group is going through the process of preparing a-----

(Interruptions).

Deputy Jonathan O'Brien: Sorry.

Deputy Richard Boyd Barrett: My other question was on EU countries that had adopted regimes with a wide access similar to what is proposed in the Bill, but the witnesses have given no explanation of what is wrong with those models and why the HPRA rejected them without argument or justification in its report and opted for regimes with more restrictive access programmes.

Acting Chairman (Senator Colm Burke): Does Deputy O'Brien wish to contribute?

Deputy Jonathan O'Brien: It is on the same issue. Chronic pain is not one of the three conditions but Mr. Lennon and Ms Egan stated that it would be open to a consultant with a patient with chronic pain to access medicinal cannabis through the original licensing system. If someone with chronic pain believed that medicinal cannabis was the only solution and his or her consultant agreed, that system would be open to him or her.

Ms Maria Egan: Correct.

Deputy Jonathan O'Brien: I thank Ms Egan. I just wanted to clarify that.

Acting Chairman (Senator Colm Burke): Does Mr. Lennon wish to add something?

Mr. Eugene Lennon: Deputy Boyd Barrett raised a number of issues. It is illegal to take a controlled drug that has not been prescribed to one. That applies whether people are taking non-prescribed methadone, which is essentially heroin, Z-drugs or benzos for pain or whatever. It is an offence, so we are then getting into the wider issue of the decriminalisation-----

Deputy Richard Boyd Barrett: Indeed we are.

Mr. Eugene Lennon: -----of controlled substances, which we will probably debate at another time.

Legislation in other countries varies greatly. I am unsure of whether the Bill is directly similar to other countries' legislation. Parts seem more similar to models to be found in North America. Ireland has moved quickly. Twelve months ago, this issue was not being discussed much. In the space of just a few months, there has been an expert report, an access programme and an expert group that is drawing up the guidelines for that programme. The situation is moving rapidly. Twelve months ago, the position was that cannabis was illegal and could not be used for any medical purpose. We are now on a particular pathway and are proceeding in what we regard as a responsible way, given that we are discussing a product for which there is not sufficient clinical evidence and that is not an authorised medicine. However, we are stepping outside the normal rules to an extent and are trying to do something in a controlled way.

Deputy Gino Kenny: May I comment on Mr. Lennon's statement? I tabled this Bill last July. I tried to consider the matter as objectively as possible and took off my political hat. That was ten or 11 months ago. Undoubtedly, we have come far. The debate has been educational for everyone involved and enlightening for the majority. We have heard heartbreaking testimonies from people who I and, probably, Mr. Lennon have met and who were in terrible circumstances. However, if this journey has only been about the cannabis access programme that the Government is promoting, that is not progress. In fact, the Department is condemning those who use medicinal cannabis to criminality. That is criminal and immoral. Other European jurisdictions have set up broader medicinal cannabis access schemes without the world falling apart or the sky falling down.

Acting Chairman (Senator Colm Burke): In fairness, we-----

Deputy Gino Kenny: This is important.

Acting Chairman (Senator Colm Burke): I accept that, but-----

Deputy Gino Kenny: In some ways, I have been leading the charge on this. This programme, given its exclusion of people with chronic pain, is flawed. The Department is criminalising people who should not be criminalised.

Acting Chairman (Senator Colm Burke): The Deputy should not be drawing a conclusion before the expert group has set up the access programme.

Deputy Gino Kenny: A lot of people have come to a conclusion.

Acting Chairman (Senator Colm Burke): We have heard the views of everyone present. Deputy Boyd Barrett asked about experts being invited to attend again. Perhaps he might write to the committee about that and the committee will consider the matter at its next meeting. Is that agreed? Agreed.

Deputy Richard Boyd Barrett: I thank the Acting Chairman.

Acting Chairman (Senator Colm Burke): I thank all of those present for contributing this morning and for their work in this area.

The joint committee adjourned at 11.35 a.m. until 1.30 p.m. on Wednesday, 3 May 2017.