DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 25 Aibreán 2018

Wednesday, 25 April 2018

Tháinig an Comhchoiste le chéile ag 9 a.m.

The Joint Committee met at 9 a.m.

Comhaltaí a bhí i láthair / Members present:

Teachtaí Dála / Deputies	Seanadóirí / Senators
Stephen Donnelly,	Colm Burke.
Bernard J. Durkan,	
Alan Kelly,	
Margaret Murphy O'Mahony,	
Kate O'Connell,	
Louise O'Reilly.	

I láthair / In attendance: Deputy Michael Healy-Rae.

Teachta / Deputy Michael Harty sa Chathaoir / in the Chair.

Foetal Anti-Convulsant Syndrome: Discussion

Chairman: In our first session today we shall meet with representatives from the foetal anti-convulsant syndrome forum, FACS, the Health Products Regulatory Authority, HPRA, and the HSE. On behalf of the committee I welcome Ms Joan O'Donnell, Ms Karen Keely, and Mr. Peter Murphy from the foetal anti-convulsant syndrome forum; Dr. Joan Gilvarry and Dr. Almath Spooner of the HPRA; and Mr. Kilian McGrane, Dr. John Murphy, Dr. Peter McKenna and Ms Cora Flynn from the HSE.

Before the meeting commences, I draw attention to the fact that 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 Chairman to cease giving evidence on a particular matter and they continue to do so, they are entitled thereafter only to a 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 are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person or entity by name or in such a way as to make him, her or it identifiable. The opening statements submitted to the committee will 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 House or an official either by name or in such a way as to make him or her identifiable.

I invite Ms Joan O'Donnell to make her opening statement.

Ms Joan O'Donnell: I thank the Chairman, Deputy Harty, and members of the committee for the invitation to present today. I am here as chair of the foetal anti-convulsant syndrome forum, FACS and I am joined today by my colleague Ms Karen Keely, chair of the Organisation for Anti-Convulsant Syndrome Ireland, OACS, and Mr. Peter Murphy, CEO of Epilepsy Ireland. Karen and I will give the opening statement during which Karen will give some insight into the lived experience of families. Peter and I will be available to answer questions that committee members may have.

Sodium valproate, or Epilim, is a drug licensed in Ireland for the treatment of epilepsy and bi-polar disorder. Foetal anti-convulsant [valproate] syndrome - or FACS - describes a syndrome that affects children born to women who were prescribed Epilim during pregnancy. Children exposed to this drug in the womb have an 11% chance of malformations at birth compared with a 2% to 3% in the general population. Malformations include neural tube defects, malformation of limbs, digits and organs, cleft palate among many, many more physical conditions. An additional 40% of children experience developmental delay and have a three to five times greater risk of developing autism, autistic spectrum disorder and ADHD. We estimate that approximately 400 children may be affected by FACS in Ireland, but just 43 have a diagnosis from the genetics department in Our Lady's Hospital for Sick Children, Crumlin.

In 2014, the European Medicines Agency, EMA, strengthened the warnings and restrictions on the use of valproate in women and girls. In 2017, the agency reviewed how these recommendations were being implemented due to concerns that EU member states, including Ireland, were not implementing the recommendations properly. In February of this year, the EMA issued additional instructions aimed at further tackling issues around reducing risk for women and girls of childbearing age.

The FACS forum asks that the Government deal with this issue on three fronts. The first is in the context of those who are already affected. We call on the Government to undertake a national study to identify how many children in Ireland are affected by this condition. An independent investigation into the historical use of valproate in Ireland is needed. A system of redress must also be established to meet the lifelong care needs of children and to address the impact of diagnosis on families. This will go a long way towards avoiding the need for legal solutions for already stressed families, some of whom are represented in the Public Gallery today and the many more who would have liked to be here and who are watching online.

The second front is the need to put in place services for families who are currently affected. Valproate-related disabilities are complex, wide-ranging and individual. Obtaining a diagnosis is difficult and lengthy and treatment often involves attending many unconnected and un-co-ordinated specialist services. Often, families have more than one child affected and full-time caring is required. It is, therefore, critical that we develop a streamlined diagnostic pathway, develop a national register of those affected and audit their needs. Most important, we must put in place the services and supports they so desperately need now.

The third front is the need to reduce the risk of children being born with FACS in the future. There is an urgent need to fully implement the recent decision of the European Medicines Agency ruling and recommendations that I mentioned earlier. We in the FACS forum have been greatly encouraged by the measures proposed, and the commitment shown by the Health Products Regulatory Authority, the HSE, and the Pharmaceutical Society of Ireland among other stakeholders. We want to see all of this progress impact on the actual numbers of children being born with FACS. Therefore, we need a systems-wide commitment that all new risk reduction initiatives will be fully monitored, fully implemented and independently evaluated and additional action taken if necessary.

Finally, we want a commitment from HSE that all women currently prescribed Epilim, especially those under GP-only care, be given priority referrals in 2018 to a specialist for an urgent treatment review. This is now required by the EMA ruling and we ask that this happens with immediate effect. I thank members for listening and I will now hand over to my colleague Ms Karen Keely.

Ms Karen Keely: I have been asked to read out some statements from mothers whose children have been affected by FACS. A mother from Cork said:

> I took Epilim when I was pregnant. My five year old son has a diagnosis of childhood autism. My son was non-verbal and he needed speech therapy he also needed an OT assessment for his sensory needs. None of these services were available to my son and my husband and I had to pay privately. The devastating impact this has had on our family is unthinkable to bear at times.

A mother from Mayo has said:

> Since the birth of my two children, never a month goes by without hospital or specialist appointments for my two children, they are 14 and nine, their disabilities range from global development delay, scoliosis, speech and language, dyslexia and physical difficulties. I had to resign in 2016 from employment to become a carer. Last December, my daughter wanted to end her life, this is the effect of sodium valproate.

A mother from Dublin said:

> The impact that the lack of correct information on sodium valproate had on my life has

> been incredible. Personally, the everyday guilt can be all consuming, and has me stuck in a vicious cycle of guilt. Every day the same questions loom... if only I had known? What could I have done differently if anything? Can I fix my girls now? What will their future hold? It's infuriating, it makes me nauseous with a mixture of emotions.

A mother from Carlow has said:

> There is no time for me and while I've come to accept this I do still realise it's not good for me, but I have to keep going. What else can I do? The constant battling for services my child has needed over the years has left me as a mother feeling not good enough, exhausted physically, mentally and emotionally. The isolation and routine of my everyday life has fuelled my depression. I cry often for myself, for my child, with my child and in frustration and anger.

I thank the committee members for hearing me.

Chairman: I thank Ms Keely very much for reading those testimonies. I now invite Dr. Joan Gilvarry to make her opening statement.

Dr. Joan Gilvarry: Good morning, Chairman and committee members. My name is Joan Gilvarry and I am the director of human medicines at the HPRA. I am joined by my colleague Dr. Almath Spooner, the pharmacovigilance and risk-management lead at the HPRA. Dr. Spooner is also the Irish delegate on the European Medicines Agency pharmacovigilance risk assessment committee, PRAC, which has been referred to already this morning. The PRAC is the committee at the EMA responsible for assessing and monitoring safety issues for human medicines. It is composed of experts such as doctors, pharmacists, scientists and patient organisation representatives from all EU member states. We are grateful for the opportunity to talk to the committee this morning about the regulation of this medicine, which is known in Ireland under the brand name Epilim. We will discuss the recent European reviews in which we have been actively involved and our collaboration with national colleagues, namely, the Department of Health, the HSE, the clinical leads in neurology, psychiatry and primary care, the Pharmaceutical Society of Ireland, PSI, and patient representatives from Epilepsy Ireland and the Organisation for Anti-Convulsant Syndrome, OACS. I would particularly like to thank the patients and their representatives for their collaboration with us over the past number of years.

Valproate-containing medicines have been licensed across the EU and in many countries worldwide since the 1960s and in Ireland since 1975. It is an effective treatment for epilepsy and bipolar disorder and for some patients may be the only treatment option. When the medicine was first approved, the prescribing information included a warning about the risk of congenital abnormalities if taken during pregnancy. These warnings were strengthened on many occasions in subsequent years as new information became available. More recently, new studies were published internationally which showed a higher than expected risk of congenital abnormalities, together with a risk of neurodevelopmental disorders in children born to mothers who had taken valproate during their pregnancy. This prompted a European-wide safety review of all the available data by the PRAC. This review was commenced in 2013 and was finalised in 2014 concluding that children exposed *in utero* to valproate were at a high risk of serious developmental disorders, in up to 30% to 40% of cases, and-or congenital malformations, in approximately 10% of cases. In the interests of patient safety, the PRAC recommended that valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments were not effective or not tolerated. The prescribing information and package leaflet for patients were updated with new recommendations around supervision of treatment by a specialist, the importance of using effective

contraception and the need for regular treatment reviews. In addition, warnings around use in female children, adolescents and women of childbearing potential, and the need for discussion of such issues with the patient, were highlighted.

Following that European review, the HPRA communicated extensively with neurologists, psychiatrists, paediatricians, obstetricians, GPs, specialist nurses, pharmacists and the HSE to emphasise the new warnings and recommendations. These communications included letters from the pharmaceutical company that was mandated by us to doctors and pharmacists, following approval by the HPRA. It appeared in several editions of our *Drug Safety Newsletter*, warnings in national prescribing formularies and on our website. Additionally, materials designed to minimise the risks with the medicine, for example, a guide for patients and a patient alert card, a healthcare professional guide and a prescribing checklist were developed and distributed. We also met patient representatives at that time and discussed it with them.

In 2017, following concerns across Europe that the measures taken in 2014 and relayed over a number of years were not sufficiently effective in increasing awareness and reducing exposure to valproate use during pregnancy, a second European-wide safety review was initiated. This review was again conducted by the PRAC which considered that these concerns were well founded. During the review, the first ever public hearing was held at the European Medicines Agency where the views and experiences of patients, including our Irish colleagues who are present today, were heard and this proved to be invaluable in the development of the latest safety recommendations. The outcome of this review has led to the introduction of new contraindications, essentially a ban on the use of valproate during pregnancy, strengthened warnings and further measures to prevent exposure during pregnancy, including a pregnancy prevention programme. The programme will incorporate measures such as assessment of individual patients regarding their likelihood of becoming pregnant, pregnancy tests before and during treatment as needed, the need for effective contraception while on treatment, and carrying out reviews of treatment by the prescribing specialist at least once a year. Most important is the requirement for the doctor to involve the patient in evaluating her own individual circumstances, to have a discussion with her on treatment and therapeutic options, to inform her of the risks and how to minimise the risks, and counselling around pregnancy prevention.

Additionally, the HPRA has mandated that the outer packaging of all valproate-containing medicines must include a visual symbol warning about the risks in pregnancy in addition to the boxed text that is already approved. The blister packs inside the outer packs will also carry a visual warning symbol. The patient reminder card will be attached to every treatment pack for pharmacists to discuss with the patient each time the medicine is dispensed. As an interim measure, pending the production of the new cartons, stickers with the warning and pictographs are being made available to pharmacies. Updated versions of the healthcare professional and patient guides and of the patient alert cards are being distributed to help support healthcare professionals and patients in their discussions on the minimisation of risk and to further ensure that all affected patients receive full and accurate information. Also, based on specific feedback from patients, the pack sizes are being reduced to packs of 30. All of these recommendations are currently being implemented in Ireland with significant progress already achieved.

Last week we published and distributed a special edition of our *Drug Safety Newsletter* to all registered doctors and pharmacists in the country and a letter was sent to relevant healthcare professionals by the company following approval by the HPRA. Over the years the HPRA has worked closely with our national colleagues, including the patient groups, the HSE, the clinical leads, the PSI and the Department of Health. Our priority at the HPRA is patient safety, and to

ensure that women and girls are aware of the very real risks of taking valproate during pregnancy. We will continue working together to facilitate timely and effective implementation of the new recommendations nationally and, crucially, to support their successful introduction into everyday clinical practice. I thank members for their time. Dr. Spooner and I are very happy to take any questions members may have.

Chairman: I thank Dr. Gilvarry and call on Mr. Kilian McGrane to make his opening statement on behalf of the HSE.

Mr. Kilian McGrane: I thank the committee for the invitation to attend this morning's meeting. I am joined by my colleagues, Dr. John Murphy, consultant neonatologist at the National Maternity Hospital and the HSE's clinical lead for neonatology, Dr. Peter McKenna, clinical director for the women and infants programme and Ms Cora Flynn, who is an advanced nurse practitioner in epilepsy in St. Vincent's University Hospital, and also a member of the HSE's sodium valproate national response team.

We would like to address some of the concerns about the use of sodium valproate medication during pregnancy. The agent, available since 1967, is widely used to treat patients with epilepsy. It is particularly useful in the treatment of juvenile myoclonic epilepsy, JME. In addition to patients with epilepsy, the medication may be used in psychiatric patients with bipolar disorders. The concerns about the use of sodium valproate in pregnancy stem from the adverse effects that it may have on the foetus. It is accepted that this drug may cause malformations and-or neurodevelopmental delay in the unborn infant. The risk of a congenital malformation is 10%. The types of malformation associated with the drug are spina bifida, limb abnormalities, cleft lip or palate, unusual facial appearance with a narrow prominent forehead and receding chin. The risk of neurodevelopmental delay is approximately 30% to 40%. There may be delays in motor development, speech delay and memory problems.

In a paper entitled Fetal Valproate Syndrome: An Irish Experience, the department of genetics at Crumlin hospital describes 29 cases diagnosed in the period from 1995 to 2016. This publication demonstrates the wide spectrum of abnormalities that can result from the exposure to sodium valproate during pregnancy. Pregnant women with epilepsy are commonly encountered at antenatal clinics. It is estimated that in Ireland approximately 400 women with epilepsy go through pregnancy each year. In the current era, it is uncommon to find that an expectant mother is on sodium valproate medication. Most are on alternative anti-epileptic drugs such as Kepra or Lamictal. The default position is that sodium valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women. There may be exceptions when no other agent is able to control seizures, for example in some cases of juvenile myoclonus epilepsy. In this scenario, the patient should be under a neurologist who can oversee, modify and monitor the treatment. Important factors are the use of effective contraception and the need for rapid consultation if the patient becomes pregnant All healthcare professionals need to be fully aware of the risks posed by taking sodium valproate during pregnancy. Pharmacists should be in a position to both explain and give the patient the "Key Facts - Valproate and Pregnancy" card. The information contained on this card highlights the risk to the foetus.

The matter of unintended consequences must also be considered. Epilepsy is a serious disorder. In the last tri-annual report for the UK and Ireland, there were 14 deaths from epilepsy in pregnancy, or 0.4 per 100,000. A patient with epilepsy should not stop her medication suddenly if she becomes pregnant. The right course of events is that she should seek urgent medical advice and be changed to an alternative medication, where possible, in a controlled manner.

On a more general note regarding foetal malformations, it should be noted that in the four-year period from 2009 to 2011, there were 136 cases of spina bifida, 121 cases of anencephaly and 31 cases of encephalocoele recorded in Ireland. Thus, one per 1,000 pregnancies is affected. Countries that have introduced folic acid fortification of food have seen a 60% reduction in the incidence of these conditions.

This concludes my opening statement. Together with my colleagues, I will endeavour to answer any questions members may wish to pose.

Chairman: I thank Mr. McGrane. Will now open the meeting to our members. We will take members in groups of three. The witnesses might make a note of the questions that are asked. Our first three members are Deputies O'Reilly, Donnelly and O'Connell.

Deputy Louise O'Reilly: I thank the witnesses for attending and for their evidence. I have a few questions. Most of them are for the HSE. There seems to be some discrepancy in the figures we are hearing. Mr McGrane talked about 29 cases as having been diagnosed. We also heard there were 43 diagnosed and potentially 400. This gets to the heart of my point, which is that there really does not seem to be much by way of verifiable data. The witnesses might explain how the numbers are collated and what they use as a measurement to decide what numbers should or should not be counted.

The witnesses might also outline how Ireland compares with other European countries in dealing with this issue, for example, in terms of the services that might be available for the sufferers and those who have been diagnosed, and also in the paths to diagnosis. There seems to be some resistance or difference there. Are the witnesses satisfied that there are sufficient systems in place now and that women are warned? I was contacted by someone fairly recently to say that she is of childbearing age, that she picked up her medication, which was in a see-through bag, and that there was no patient alert card with it. How is it policed? How does the HSE ensure that when it is issued, the alert card actually gets to the patient? I think the witnesses will accept that it has not done so in all cases. What penalties are there for people who do not comply with a patient alert card? I am sure everybody wants to comply and do their best. Is there any penalty?

Regarding the victims of this, Dr. Gilvarry mentioned the 1960s and 1970s in her statement. She stated that new studies have been published more recently. It strikes me that there is a fair amount of information available that would have set off alarm bells. Dr. Gilvarry might elaborate on exactly what she meant by "more recently". I am interested in when the risks were known about, how serious the level of knowledge would have been, and how it was communicated. I think there are doctors who would have prescribed in good faith without being aware at all that there was an issue. There may have been a time when there was some awareness among the medical community that there may have been a risk, but it might not have been widely known. Then there was a period, which I would be interested in exploring with the witnesses, when the risks were very well known and the prescriptions continued. Those women's children would now be in their 20s and 30s and they are dealing with a range of complex and difficult conditions. As was outlined, the women very often have more than one child in this situation. Perhaps the representatives from the HSE might outline for us what is in place for them. Is there a specific package or are they simply in the mix with everybody else, trying to scrap it out for the services that are there? Or, as was outlined by Ms Keely, do they have to go to the private sector to purchase services that should be available in the public system? What specific packages are in place and how can they be dealt with?

I may come back with other questions at a later stage if that is okay.

Deputy Stephen S. Donnelly: I thank the witnesses for attending. I convey particular thanks to the FACS and to Ms Keely for giving voice to what the parents and children have been experiencing. It has been heard. My first question is for the forum. There is clearly a lot of co-operation between it, those who have been affected and the relevant agencies of the State. Do the forum members believe that the State bears any liability for what has happened? What services are they not getting? Do they have a sense of the kind of costs that are being incurred by families supporting children who have been affected?

For the HPRA, is it possible to establish a causal link in an individual case? There are shocking levels of causality that can be found through clinical testing but, on the basis of an individual case, is it possible to say that a particular boy or girl has physical or neurological issues that can be causally linked to the drug?

I ask the HPRA and the HSE why there have been so few diagnoses. If approximately one tenth of the estimated number has been diagnosed, why is that figure so low? I ask the HSE what the response has been to the requests that have been laid before the committee this morning from the FACS. It has requested that there be a study on the number of children, an investigation into how this happened in the first place, and that the services required be provided. As Deputy O'Reilly said, the parents and children are not looking for a slice of a finite pie. Is there a package that has been put in place? Is there any estimate of the cost to the State of providing the required services or the cost per family or child? Mr. McGrane mentioned children not reaching full potential as a result of neurological development delay. Does that mean the child will reach his or her full intellectual capacity but take longer to do so, or that the child or adult will have a permanent intellectual issue?

I have a question for the representatives from either the HPRA or the HSE. Mr. McGrane stated that it is now uncommon for the drug to be prescribed to pregnant women. Given the evidence before us that 30% to 40% of children whose mothers used the drug during pregnancy have serious issues, is there a clinical reason it is still prescribed to some pregnant woman? If its use is uncommon among pregnant women, some are being prescribed it. Is there an overriding clinical reason that makes the risk worthwhile in those cases or has its usage by such women not been eradicated because not all prescribers are fully aware of the dangers?

Deputy Kate O'Connell: I thank all present for attending, particularly the witnesses and the parents of affected families. My view is that, regardless of the causes of the conditions the children have, the State has responsibility to assist those children and their families. I am a community pharmacist. I have dispensed valproate for years and have long been aware of the congenital issues with the prescribing of the drug. In many cases women have been stabilised on the drug since their teenage years and then start a family. My understanding is that there was a failure in the counselling of women who were taking valproate as to the appropriate treatment for them in regard to a transition from not wanting a baby to starting a family. Are the HPRA and the HSE happy that that failure has been rectified and there is no chance that any woman who has been long stabilised on valproate will slip through the net and not receive the appropriate counselling? For some patients, it is the only product that will keep their epilepsy under control. That causes a serious problem when such people want to start a family. Decisions must be made in such a situation. Changing the medication of a woman who is stabilised on epileptic medication while pregnant could be very dangerous to the mother and the developing life in her womb.

As regards the EU-wide response, are the Department and the other witnesses happy that the response in Ireland was as fast and robust as that of our European counterparts? Are we at the same level as other countries in that regard? Much information and many bulletins, stickers, leaflets and so on have been sent to community pharmacists and I am very happy to see that happening. However, it is clear that did not work in the initial phases. The HPRA statement indicates that the first interventions to get this information out did not have the desired effect. However, it was done again and seemed to have a better response. Has there been an assessment of what might be a better response were this ever to arise again? Is the dissemination of information to patients on this medication best achieved by sending stickers, leaflets and cards and educating pharmacists and GPs? I suspect that, in this day and age, that is not the best way to make an impact.

As regards the continued review of the product, it is now clearly linked to congenital disorders. It is very important to point out that it has been so linked since it came on the market. However, there has been a marked rise from over 10% to 40% in the number of people who have developed mental issues. What is being done? In the case of drugs such as isotretinoin, also known as roaccutane, the initial recommendation was that they should not be used by women of child-bearing age, followed by a recommendation that prospective fathers should not use them. Are the witnesses considering the effect of valproate on sperm generation? Many girls on the medication were exposed to it *in utero*. Are such girls now grown up and have any studies been carried out on the effect on their reproductive systems? Is there any information on the effects on the offspring of mothers who were on the medication?

Ms Joan O'Donnell: I will deal with the questions regarding State responsibility, services and costed services and then hand over to Mr. Murphy.

We must consider the issue of the State's responsibility. We recently met the Minister for Health, Deputy Harris, and clearly informed him that, as we understand it, the State bears the responsibility to ensure that women and children who have been affected by this drug get answers in terms of accountability. The Minister has committed to get back to us by the end of May and consider the issue of compensation. My colleague, Mr. Murphy, will be able to tell us more about what is happening in other jurisdictions on this issue. France and the United Kingdom are very much moving in the direction of compensation. There is a mismatch between when the dangers of the drug were known and when patient information leaflets were changed. There is a huge culpability and liability since 2014, when the EMA had made a ruling but that was not being implemented by a state. There is clear accountability since that ruling. This was the first time the PRAC revisited a drug on which it had made recommendations in order to ensure that those recommendations were being properly implemented.

Yesterday, we heard of a woman in Cork who collected her medication in a plastic bag without a label. It is a similar situation to that earlier referred to by Deputy O'Reilly. There must be an investigation into this matter. We must understand who is responsible. The families and parents affected are under enormous stress. As we explained, they are going from Billy to Jack in terms of getting services for their children. There is no co-ordination of services. It is extremely difficult to get a diagnosis and many people are leaving work in order to care for children. The costs are both unbearable and unmanageable. It is not for us to quantify them. We are an unresourced body trying to advocate on behalf of women and do not have the resources to carry out that sort of cost analysis. There is financial cost but also a cost in terms of lives, quality of life and lost and damaged relationships. The costs to people's lives are immense. We must establish accountability and make some retribution or redress on that basis. We hope that

there will be a cost analysis on the Cumberlege report, which has just been issued in the UK, because it has been resourced. As far as I am aware, there has been no resource put into this here. I will hand over at this point to Mr. Murphy.

Mr. Peter Murphy: On Deputy Donnelly's question regarding the State and its responsibility, it is important to reiterate that these disabilities are not bad luck or random incidents, they have been caused for reasons other than chance such as exists in the general population. Our overall position is there is a huge public interest reason as to why this issue should be investigated. Rather than us coming here today and saying X or Y is responsible, what we need is an independent inquiry to look into these questions and come up with answers. There are a lot of parties that would need to be involved in that discussion.

As for what is happening in other countries, the UK recently announced a review of this drug and a number of other products and drugs with a view to determining whether the State has responded adequately over the years to safety issues. As part of this review, the issue of a compensation scheme is being examined. France has gone a step further in that the state there has accepted its responsibility and established a compensation fund of approximately €10 million. The French Minister for Health has acknowledged that this is merely a starting point. Crucially, in France there have been moves to involve pharmaceutical companies in the process. As I understand it, if the pharmaceutical companies do not make an offer of compensation to an individual then the state will cover it. Obviously, the legal system in France is different to ours.

Deputy O'Reilly asked when the risks were known. I am sure the Health Products Regulatory Authority, HPRA, will have more information on this but from our point of view foetal valproate syndrome was first reported in the early 1980s and it was well established and accepted by the mid-1990s. There was a key paper on this in 1995, which outlined the many different symptoms that could have been experienced. It was in the early 2000s that the link with developmental delay, autism and ADHD became known. We have reviewed the information that was provided on the summaries of product characteristics, SPCs, which are the documents provided to pharmacists and healthcare professionals about drugs and we have found discrepancies in terms of reporting of risks on those materials compared to the data that would have been known at the time, as well as some variances between what was on the UK data sheets and what was on the Irish data sheets at the same time. These are all issues that could be looked at as part of an inquiry to establish what may have happened over the years.

Deputy Kate O'Connell: Can Mr. Murphy elaborate on the point regarding the differences in the data sheets between the two countries?

Mr. Peter Murphy: For example, there is an increased risk of polytherapy with valproate in pregnancy. From what we can see, this was first included in UK data sheets in 2002 but not in Ireland until 2008. From 2001, in the UK it was recommended that Epilim be used in women of childbearing age only in severe cases or in those resistant to other treatment but a similar recommendation was not in place in Ireland until 2012. There were a number of other discrepancies. Historically, the information has been available in the data sheets but ten or 15 years ago, that information was minimal. It has since expanded over the years. The question is whether it has always reflected everything about a drug that has been known and accepted.

Chairman: Would Dr. Gilvarry like to comment?

Dr. Joan Gilvarry: I will ask my colleague, Dr. Spooner, to answer the question about the studies that led to the European review and to some of the other questions.

Dr. Almath Spooner: I thank members for their thoughtful questions, which I will try to answer as sequentially as possible. Deputy O'Reilly asked how we will monitor impact, which is a critical question because as well as looking back and learning lessons, we need to work together to ensure that future generations are protected. It is important to emphasise that at this point, we have taken the most definitive regulatory step possible. We have contraindicated the use of sodium valproate - Epilim - in women of childbearing potential unless the requirements of the pregnancy prevention plan are followed. Following amendment of the licence, it is now a requirement of the licence that the pregnancy prevention plan is implemented, which is an important change. We have tried communication. We are moving from process to impact. The objectives and the goal of risk minimisation is that women of childbearing potential will have full information on the risks, with the overall goal being that exposures and pregnancy are avoided. We do not want to see future children harmed by this medicine.

Deputy Louise O'Reilly: On amendment of the licence, has that been done?

Dr. Almath Spooner: This is a European story. As members have acknowledged, the European decision-making process finalises with the European Commission decision and those administrative steps are ongoing. The recommendation is firm. It is just the physical changes to the documentation that have yet to be made. It is in the process of being finalised. In this regard, we are speaking about weeks or months rather than any longer.

Deputy Louise O'Reilly: Would Dr. Spooner like to comment on the issue regarding the woman in Cork yesterday? It would appear that the regulations are not having the desired impact. Practically speaking, how will this translate into action? I am sure that like me, other Deputies have been contacted by women of childbearing age who have been prescribed this medication but have not been alerted to this issue.

Dr. Almath Spooner: That would be a concern for the HPRA and all of us working to ensure that these medicines are used safely by those who need them but not in pregnancy. We will be working collaboratively with patient groups and the HSE on this issue. We received notification last week from the Health Research Board in regard to an application in which we sought to do academic collaborative work with the RCSI that would bring some independent perspective to analyse drug utilisation data to make sure that these measures are effective in practice. I appreciate that members will have anecdotes of situations where practice needs to adapt. We need systematic evidence to be generated to ensure the measures are working in practice and that women who are at risk are not being exposed. We will be undertaking this work with patient groups and academics.

The pharmacovigilance risk assessment committee, PRAC, was established in 2012. It was the product of amendments to European legislation, which I am sure many members have followed. PRAC was established as a committee independent of the licensing committee. It was given regulatory teeth and its outcomes are binding. At the time of its establishment, recognising the public health importance of this issue, this was one of the very first reviews we did. I am vice chairman of that committee and I am doing all I can to make sure that this is robustly addressed in terms of analysing the scientific data but also following through on other issues. As rightly said by my colleagues, this is the first example of a referral in which we have undertaken a look-back in terms of whether measures are working or if we need to do more and the answer was yes. We can only do that using a collective multi-stakeholder approach. We regulate the products and now need to ensure the knowledge of the harm associated with the medicine leads to changes in clinical practice.

I emphasise and acknowledge that we are talking about a chronic condition. Deputy Kate O'Connell referred to Isotretinoin, but members will appreciate indications and population. Acne is very different from epilepsy. We have concerns and do not want to have unintended consequences. Switching a woman's prescription from sodium valproate to an alternative requires time, but it requires specialist expertise, in particular. That is why the PRAC has made it a requirement of the licence that an annual review be conducted by a specialist when sodium valproate is prescribed for women with a credible risk of pregnancy. That is not a provision attached to a licence lightly; it is simply to recognise the importance of the health risk.

Some Deputies addressed the common theme of why identifying the risks had taken so long. As the congenital defects are visible, members can understand why they were identified early on. Warnings about such risks were issued right from the beginning. However, as neurodevelopmental disorders are more subtle, it takes time to make a link with exposure *in utero*. Deputy Stephen S. Donnelly made an astute observation on delays, but I wish to emphasis that we are not talking about delays but disorders. The PRAC has clearly outlined that they are disorders where children do not catch up in their development. That is something that came through very clearly in patient testimonies. We understand the magnitude of the risk. We understood there was the potential for harm if sodium valproate was used in pregnancy. What we have seen over time is an evolution in the understanding of the risk and its magnitude and the impact on children and their families. That understanding has been facilitated by the fact that, as a committee, the PRAC has focused on hearing directly from patients. It has both a public health focus and a patient engagement focus. The way we conduct pharmacovigilance today differs greatly from how we did so in the 1980s. One aspect is the new data streams, a new willingness to engage with patients to hear about their experiences.

Another aspect is the epidemiology evidence required to make a link. That evidence was unavailable in the 1970s and 1980s. The first of the research papers came through around 2008. It was a Meador et al landmark study which, as some Deputies mentioned, provided the most robust evidence of a causal link between neurodevelopmental problems and the treatment. There is convergence and an acceptance of the risk. As Deputy Stephen S. Donnelly mentioned, it is difficult to make a causal link at an individual patient level. However, we know, based on the epidemiological studies, that 11% of patients have physical defects and approximately 30% to 40% have neurodevelopmental problems, within which there will be a spectrum, by which I mean that some patients will be more severely affected than others. The data stream on which we have relied is the epidemiological evidence, rather than trying to make individual causality assessments which, by definition, is very difficult.

On the questions posed by Deputy Kate O'Connell, I hope I answered her question about referral to a specialist for an annual review. I have explained that when treatment is initiated, concern about harm in pregnancy might seem a remote concern. That is why, as part of the global package of measures, we have advocated for the avoidance of the use of sodium valproate in young females, with a view to reducing the complexity involved for individual patients, given all they could suffer in the healthcare system in having to ultimately transition from one treatment to another. Our goal into the future is to prevent exposure to sodium valproate in pregnancy. At one of the stakeholder meetings Mr. Peter Murphy of Epilepsy Ireland said we must move beyond process to impact. My organisation is in full concordance with him on that point.

Deputy Kate O'Connell: Why was there such a difference between the United Kingdom and Ireland in terms of inclusion in data sheets, as mentioned by Mr. Peter Murphy? That

was unusual. Why was there a discrepancy in the information included? As outlined, in 2002 information became available on the summary of product characteristics, SPC, in the United Kingdom but it did not become available here until 2008. Who has responsibility? Does it rest with the HPRA as regards individual member states or the maker - Sanofi?

Dr. Almath Spooner: It is the marketing authorisation holder. Will the Deputy allow my organisation to consider the comparative analysis as it would be remiss of me to respond without having the details in front of me? The general process is the marketing authorisation holder submits a variation to us; we assess it and one anticipates that the company, as a global company, will submit variation to all of the regulatory authorities.

Deputy Kate O'Connell: Yes.

Dr. Almath Spooner: Also, it would have been an agent that would have gone through the EU referral process by the licensing committee, the Committee for Medicinal Products for Human Use, CHMP, for the harmonisation of product information. We would like to understand why historically there might have been some differences. We need to carry out a piece of work to analyse whether there were substantial differences. I am sure we will be happy to discuss the matter with Mr. Peter Murphy and his colleagues and update the joint committee should it be necessary to do so.

Chairman: I thank Dr. Spooner. I will call two members who have not contributed to the debate so far. I call first Deputy Bernard J. Durkan who will be followed by Senator Colm Burke.

Deputy Bernard J. Durkan: I thank the Chairman. I welcome all of the delegates. We are all concerned about the tragic consequences and the effect this matter has had on individuals and their families. Which country first identified the seriousness of the risks involved? There appears to have been strong support for the drug in Scandinavian countries, but I am not sure whether that remains the case. The drug is still recommended and used in Iceland. I know that it was used or used in combination with something else in the 1960s. Some body somewhere first detected its negative aspects and I would like to know more about the matter.

Why, when it was first discovered, was no Government health warning issued? I am not necessarily referring to the Irish Government. The international community should have recognised the potential risk and applied a health warning to protect both patients and the professionals who might have found themselves in the position of prescribing the drug in certain circumstances.

Is the drug permitted for use in all European Union member states? Do containers containing capsules or tablets display warnings? If so, when did that take place? Is the matter in hand?

Negative side effects have been identified. How long did it take for a warning to be issued to all member states and practitioners throughout the European Union? It is important that we know such information.

There are alternatives. What are they and how effective are they? Have they been prescribed and recommended for use throughout the European Union? Have they been prescribed and recommended for use in this country? Have GPs and consultants been advised of their potential use and to what extent have they been so advised?

On the HPRA's response, it appears on the face of it that matters were beefed up to European

speeds. However, I do not know and would like it to be confirmed.

With reference to European agencies, on many occasions we have discussed the effectiveness of the Irish system versus the European system and the need to have one overall system to provide for the Rolls-Royce tests. Has that taken place in this instance? In the European system, tests should be well ahead of everybody else and should be on a par with the best internationally.

It was 2009 when some concern arose at European level. Were warnings issued throughout the system to all European countries? If not, why not? Were there any discoveries by the HPRA in Ireland?

In October 2013, when the concerns were obvious to everyone, how effective a warning was issued throughout the system, to doctors and patients who might have been recipients of this treatment? How quickly was the warning issued and how effective was it and was it sufficient to alert people to the seriousness of the situation? Herd protection is one thing but individuals have rights in all systems. It is not true to say that it was tragic - which it is - but necessary. There are alternatives, and they need to be examined and treated as equally effective treatments.

Senator Colm Burke: I thank the witnesses for their very comprehensive presentations. I know some of them face a difficult task in dealing with this issue.

Some of the issues I wished to raise have been raised already so I will be brief. According to the presentation, since 1993 there are about 400 children with developmental delay and about 100 with physical malformation. Do we have accurate figures, including for the number of families affected? Are there situations where there might be more than one child in a family affected? Every child needs support but it is something that needs to be examined at the earliest opportunity and to ensure that those families have adequate support. I am interested to know how many families need support now? What further work needs to be done to try and establish a very accurate figure on this so that the supports can be put in place?

I have a general question for Dr. Gilvarry on the overall process in regard to medication and medicines in Ireland. Over the last two years, we as a committee have come under a lot of pressure to make sure that medication, if one can call it that, be made available in cases where there is no clear scientific evidence that it does not have detrimental effects in the long term. Here, we have a situation where we have medication that has gone through all the research and development, has been in place and working for 25 or 30 years and problems are arising with it. Is any process to review medications available in Europe or Ireland, where even if a product is around for 20 years, we might need to review it occasionally? I know it would be a difficult task because there are so many pharmaceuticals on the market. Just because a product solves some problems, that does not mean that it might not cause others.

When a problem is identified in Europe or Ireland, have we a process that reacts fast enough when deficiencies in what is being provided are highlighted? Big pharmaceuticals are very well able to defend their positions and they have the power of public relations to ensure that any deficiencies found in a medication are downplayed. They can put their own pressures on bodies, including us as Members of the Oireachtas that we should back off on raising queries on the issue. Have we sufficient red alert systems in place? Is there a need to be far more proactive in that area? There are so many medications available and we have an issue where one medication may not go with another. Medical practitioners are always under pressure, and trying to keep them up to date is difficult. Have we done enough in this area? We might criticise the HPRA

sometimes for not processing a product fast enough and we must be careful to make sure that when products are on the market, they deliver what they say they will.

We need to look at these areas. There seems to have been a delay in this case. The information did go out but it is about it going out to the relevant people and being effective in getting the message across to them. I am not clear about whether the way we did that messaging was effective.

Chairman: I apologise for having cut Mr. McGrane off earlier. He now has the opportunity to answer all those questions.

Mr. Kilian McGrane: I will ask my colleague, Dr. John Murphy, to deal with the discrepancy between the cases referenced in the study here and what Ms O'Donnell said about confirmed diagnosis. He might also respond to Deputy Donnelly's reference to why there are so few diagnoses.

Dr. John Murphy: Deputy O'Reilly hit upon a very important issue on the discrepancy in figures. There is always a problem with data collection, in how it is collected and how we centralise the collection of that data, particularly when a drug has a number of side effects. If it clearly had one side effect, and one side effect only, one would imagine that the relationship would be very clear but this one was different. Sometimes it causes a physical disability, other times it causes a problem with a child's learning abilities and so on. Those are very different issues. The other problem about malformation is that it varies. For instance, a child might be born with a cleft lip or palate and will go into the service with plastic surgeons, or a child will be born with spina bifida and will be sent off with neurosurgeons. A child might have a hand or thumb deformity and will be dealt with by an orthopaedic surgeon. It means that early on, the children will go off in very different directions. How it will happen that the relationships will be made, and how it is reported centrally, or will it be reported back to the company which makes the drug is an important issue.

If the child only has neurodevelopmental problems, they will not manifest early on, they may only develop and become apparent in the second half of the first year when the child is a toddler. That is well after the pregnancy has ended and the relationship may not be remembered or enough emphasis might not be placed on it. That leads to discrepancies.

With an agent such as this, one needs an association, for starters, that someone has been on a medication during pregnancy and now it is associated with a problem with the child. One has to look to see if the relationship is clear and the child does not also have some other underlying problems. That must be tightened up in the future. Geneticists are the key people to bring closure on a place and to decide that, one needs a genetic input. As a specialist, I might identify the problem and know there was an association with Epilim, I will put it together but get a geneticist involved to ensure there is no other factor that could have affected the child in the womb, and that no other cause for the malformation occurred in the womb. That is an important area.

We described a series of 29 cases which were very carefully reported by the group in Crumlin. That is the kind of model that we would need.

Someone asked what is happening in other countries. I was speaking to a colleague who is a geneticist in the United Kingdom. They have processed and evaluated 100 cases. That would need to happen. We would need to collate cases where parents have had the issue of Epilim in pregnancy and they have a child with challenges or difficulties. They would have to go through

the system to ensure that the diagnosis is correct for their sake and establish whether the children have some other problems as well. It would be a great help if that could happen. There is a model there but we will need clearer figures in future because that has been an issue.

Deputy Louise O'Reilly: Ms O'Donnell gave evidence suggesting that approximately 400 children may be affected by foetal anti-convulsant syndrome in Ireland but that only 43 have diagnoses. Does Dr. Murphy agree with that figure?

Dr. John Murphy: I do not know. It is hard because the figures come from varied sources. Someone made the point that cases involving babies who have had a physical malformation are more clear-cut because they occur earlier on and perhaps come to greater attention because the baby is in the hospital setting and the specialists all see the child. That is far more likely to be processed and documented. Let us suppose a child goes home and seems to be okay and is out in the community. Then let us suppose something is picked up by the public health nurse, for example, something not progressing satisfactorily for a toddler. Alternatively, something may be picked up by school teachers if a child is not doing well and needs a special needs assistant. That is some years down the road. How does that come to the surface? That may be among the challenges we are faced with. Obviously, others have opinions but I am suggesting a pathway to approach it.

Deputy Louise O'Reilly: There is an extraordinary disparity in the figures given the difference between 43 and 400. Let us suppose we are trying to access the potential scale of the issues we are dealing with. One figure is 43 and another is 400. Which figure is closer to what would be the average number per head of population in another comparable country?

Dr. John Murphy: It is difficult to say. We will get a good handle on those cases involving a physical disability early on. For children who have learning disorders and so forth, it is going to take more time to work out the true picture because that has only emerged. The issue of learning problems and disorders has become more clear-cut in recent years. That is going to be difficult to establish.

Chairman: Does the HSE have the potential to create a register of patients? If a mother or parent suspects that a child has a difficulty relating to taking Epilim in pregnancy, could there be a central location to register the suspicion? Could that then be taken up by the HSE? Could the HSE act as one point of contact? Could people access services depending on what their disability is and whether it is neurodevelopmental or physical? There could be the possibility of a register where a suspicion could be lodged. The HSE could then take it from there instead of people having to go to several different services.

Dr. John Murphy: I think that would have to be set up. The word "register" brings to mind continuity. A register is not simply a once-off thing that someone establishes today with the relevant children as things stand. The register would have to be there in future to capture any future cases that might arise. That is a clear point about registers. They are not much use unless there is a commitment to them in future. I suspect we would need someone to co-ordinate it nationally. In my hospital, there are 40 or 50 women who have epilepsy and who are attending the antenatal clinic. I speak to the obstetricians who work with me. They tell me that, at the moment, few or none of the patients are on Epilim. That is mirrored throughout the country. Let us assume that approximately 400 women throughout the country may have epilepsy when going through antenatal clinics per year. It is important that they are surveyed from now on to find out whether any of them are on Epilim for an reason, whether from a psychiatric viewpoint or an epilepsy viewpoint. They are the ideal group that should go into the registry. We may

have two processes in parallel. One could look at any pregnancies now and in future. Another stream of work could examine what has happened to the pregnancies in cases where mothers had been on Epilim, what happened to their children and whether they have any physical disability or learning disability.

Deputy Louise O'Reilly: Dr. Murphy might be able to talk to us a little about whether that would be possible in terms of the register. I appreciate that it would be significantly easier to start from here, but that is not going to change. We heard about the 1960s, 1970s and 1980s. Would that be possible? Is that something the HSE is considering?

Deputy Stephen S. Donnelly: Before we finish with Dr. Murphy, I have a question on the same topic. It is relevant for the parents who have already come through this. Is Dr. Murphy stating that genetic testing could be done that would essentially establish a causal link? Would that allow mothers and fathers who have a child and who are suspicious to advertise nationally? Let us suppose a woman was taking Epilim before or during pregnancy and a child has a developmental problem. If that woman makes herself known to the relevant person, can we test using genetics? Is that what Dr. Murphy is saying?

Dr. John Murphy: The question is whether the agents have been taken during the pregnancy and whether there is an association with a child having a problem. What we need to do is exclude any underlying cause that may affect the child's health by a series of tests. Then we need to make a reasonable assumption based on that and either genetic testing or chromosome analysis such as microarray or other modern tests. Finally, we need to establish whether the pattern fits. The type of physical anomalies that these children have are key points. The shape of the forehead is one such anomaly and there are other issues that parents would be aware of as well. The idea is that we could put together a reasonable picture of what happened and whether a relationship really does exist. That would be helpful to families who have a child with a problem. They need an explanation - an explanation is so important. From there on, we could work towards what is best to maximise the child's potential and well-being. That is the way forward. We identify the problems and often treat them in the newborn period. The key to making the final link is a geneticist opinion.

Dr. Peter McKenna: I wish to answer Deputy Donnelly's question. One could advertise and get a large response, but the genetic services are already overwhelmed and have a major backlog. What we could do and what we can do are separated by the number of geneticists and the extent of the genetic services, which are already struggling.

Deputy Stephen S. Donnelly: Could the work be outsourced?

Dr. John Murphy: We could appoint another geneticist. That has been done before. We have had issues like this previously. We have had to appoint additional neurologists to look at other issues. There could be a task force or a system to look at the cases and process the group of children. Reference was made to the difference in the numbers. We could look at the gap between the numbers known about and the numbers that potentially exist.

Deputy Stephen S. Donnelly: I am keen to explore the point of whether technically we could do it versus whether we have the human capacity to do it.

Dr. Peter McKenna: We could probably send the laboratory tests abroad but, ultimately, much of this will come down to the expert assessing and looking at the results and looking at the clinical problem. One could not send the results abroad, get a result and then solve the problem.

Deputy Stephen S. Donnelly: This is a single batch of work rather than steady-state work. A set number of people need to be evaluated. Is it possible to hire in from-----

Dr. Peter McKenna: I doubt it.

Deputy Stephen S. Donnelly: Let me finish the question.

Dr. Peter McKenna: The human element is such that-----

Deputy Stephen S. Donnelly: I want to finish my question. Are there private companies or, potentially, publicly employed experts abroad who could be hired in for a set period to do the testing and assessment?

Dr. Peter McKenna: I do not know the answer to that.

Dr. John Murphy: The relevant people have had experience in the United Kingdom. Certainly geneticists have been involved there. The committee could inquire into that. However, I think the point my colleague is making is that there is a major human element all of this and these children would have to be seen by specialists in Ireland. We do not want these children going somewhere in the United Kingdom. That would be very disruptive for the children and the families. Whatever happens should be done in our country. Then the individual who is seeing these children can make directions about how best they should be treated in future. The key thing is to look after these children in the best way possible.

Deputy Stephen S. Donnelly: It is based on the very small size of our population, relative to the types of resources available in places such as Canada, the United States of America, France, Germany, Austria, Finland, Sweden, Denmark and so on. I cannot imagine the resources these countries deal with based on their populations. I have no idea but we are talking about a very small number of people relative to the scale of these other countries and the resources they have. This might be worth getting a view on.

Dr. John Murphy: The point the Deputy is making is that the lessons have been learned from what other countries have done and we need to look at how they set about the process in the most effective way possible, described by the Deputy as the pathway, for these children and their families.

Deputy Louise O'Reilly: We need to examine the difference between the 400 and the 43. Perhaps Mr. McGrane can outline for us exactly how the HSE will do that.

Mr. Kilian McGrane: A question was asked earlier about whether or not there were effective pathways for those who are affected by this. During the course of the discussion today members have heard about the complexities involved in confirming a diagnosis and in the range of different service needs sufferers may have, from neural developmental to physical. This poses some of the challenges. Ms O'Donnell said that the FACS met the Minister and he had written to the HSE and has asked about the various clinical leads in the different areas - we can see the multiplicity of disciplines involved in providing care in this regard - and that we would meet the FACS and start the process of identifying the needs and in looking at care pathways. The witnesses are correct when they say we must establish what the population we are dealing with is. We are hoping that it is a static population as the procedures outlined today are minimising the risk of future occurrence. However, we have people whose lives clearly have been massively impacted to date and we need a process for managing them. To do this, as has been said, we need some form of register. Dr. Murphy spoke of the value of a register and that it

runs into the future and is not a static snapshot in time. It is about creating and understanding, so we can deal with all the factors. The process has started. I cannot give the Deputy a definitive answer because some of the questions are about the confirmation of diagnoses and we do not have the answer to this yet. Once this information is established the issue of the register becomes easier to manage, in the current phase and into the future. The development of the pathway will start as soon as we have the engagement with the right clinical specialists and with the FACS around the needs that have been identified to date. The FACS is very articulate in putting forward its views, and from this I presume that affected children are being disseminated into the wider system. There is no care worker, for example, dealing with specific needs and the families have to find the services where they are, which in many cases means there would be deficits in the services.

Chairman: Is the issue about developing a clinical diagnosis as opposed to a genetic diagnosis? Is this not the issue that the parents of children are coming up against? They cannot get a clinical diagnosis because there is not a central point of reference where they can present their case.

Mr. Kilian McGrane: That is a good point.

Dr. John Murphy: The pathway is not firmly established for them. The children will come from a number of primary specialists who deal with the immediate problem the child has, be it a physical disability, psychological issue or learning issue. They will come from a number of different sources. There needs to be somebody in a position with sufficient information and knowledge to be able to finally and definitively say: "This is a case of this disorder." It then kicks on from there. Diagnosis makes a big difference to a child and a family. Once they have a clear diagnosis, they can move forward as they are not looking for the diagnosis anymore. It has been established and they can move on into the therapies and supports they need. That is a key point. It unlocks the door for these families. This is where it is currently in the State. This is why there are discrepancies in the numbers. One would like to think that with a bit more effort and work we could come back here with the totals for the number of children who have been affected in the past, there is a register in place and any future children born to mums who have Epilim during pregnancy will be monitored very carefully.

Chairman: I will let Dr. McKenna come back in, then I will ask Ms Joan O'Donnell for a comment and then I will bring in the Senator.

Senator Colm Burke: Can we set up a process for dealing with this? The problem seems to be that there is no process for dealing with it.

Dr. John Murphy: There are a number of parallel groups. We in the clinical lead programme in paediatrics and neonatology were contacted by the HSE to look into the matter. We are setting up a meeting shortly. We are bringing together a group of consultants and specialists who deal with children with these types of disorders and the relationship with Epilim to see what we should do to best progress things. We will meet in the next few weeks to try to progress things rapidly. I am aware there are a lot of issues and anxieties around it.

Dr. Peter McKenna: There is not always diagnostic certainty about this. Dr. Murphy has also said this. If a mother was on a high dose of Epilim and a child was born with an obvious physical abnormality such as spina bifida, then it is entirely reasonable to conclude that one has led to the other. If, however, a mother was exposed to a low does for a short period of time during the pregnancy and the child subsequently developed a behavioural disorder, it is much more

difficult to attribute the subsequent behavioural disorder with absolute certainty and clarity to the small dose of sodium valproate to which the child was exposed for a short period of time. This situation is not like many diagnoses that are absolute, where one can say "Yes" or "No". There are degrees of greyness and subtlety here that will need to be borne in mind.

A possible explanation for the difference between the 400 and the 40 is that the 400 might refer to the number of women who took the medication during the pregnancy and whose babies were exposed to it, while the 40 refers to the number who have received the absolute diagnosis. I speculate when I say this but it would appear to be the most reasonable explanation for the big disparity between the 400 and the 40.

Ms Joan O'Donnell: I will respond to some of the figures very briefly and then Mr. Peter Murphy will come in also. The 29 cases referred to in the report were just the number that the study looked at. Our figures, from Professor Andrew Green, chief geneticist in Our Lady's Hospital for Sick Children, Crumlin, tell us that 43 cases have been diagnosed that have come through the genetics department at Crumlin hospital. Professor Green also tells us that this figure does not include anybody who was not diagnosed via that and who may have had spina bifida, for example. The estimation of 400 children affected is one we ran by Professor Green. We extrapolated from the UK figures, where an estimated 20,000 children have been affected. We looked at the figures over the course of the years since Epilim was introduced in Ireland and we also made allowances for the declining prescription figures currently. We are happy to share this figure for estimation, which is the most robust estimate we can make at the moment. We have had some medical opinion on it and they seem to concur that the figure of 400 looked about right.

I will now turn to the issue of diagnosis. The HSE's perspective in this regard is from a clinical point of view. I totally understand that the HSE representatives here today are looking at the complexity of the issues and grappling with how difficult it can be to diagnose, but I also want to put a parent's perspective on it. Parents know their children best. They very often report to us that their concerns about their children are dismissed, that their expertise in regard to their own children is ignored and that they are batted back out of the system. We also hear that parents are going to France, Northern Ireland and other jurisdictions, including the UK, because there is a two year waiting list here. We are concerned that perhaps there may be a reluctance to diagnose because of the complexity of the issues. These are all aspects that we need to get over. We need to create a comprehensive system of supports and a clinical pathway for children who are affected.

Mr. Peter Murphy: With regard to the numbers and where the numbers come from, Ms O'Donnell has made the point, but I want to highlight the real significance of gathering the numbers as a very early step in this process. I am aware it has been discussed a lot here. A register is already in existence at Beaumont Hospital, which is an epilepsy and pregnancy register. It is a national register and this is being mooted by a number of parties, including the Department and the Minister, as a potential solution to this. There are a number of challenges to overcome but the infrastructure is, potentially, already in place. It only gathers data relating to epilepsy and does not gather bipolar information. It also only gathers the information for a limited period after a child is born. The key issue with the register is that for many years it has not been funded by the State but by industry support, which has recently run out. With investment by the State, there is a framework and an opportunity to transform and expand an existing register to gather data on pregnancies and information on individuals affected, as well as their treatment needs and the effectiveness of their treatment.

We were asked whether we were up to speed in Ireland. In our response in recent times we have been very much up to speed and the HPRA has been very proactive, as have all parties, in addressing the risk issues. The key point in respect of the risk for the future is that a lot of things were done in 2014 and a lot of boxes were ticked at that time. A lot of letters were sent out and information materials were developed and distributed by the HSE and the drug company. There were drug safety newsletters and changes to patient leaflets and everybody is now aware of this, including specialists and pharmacists. Sending out information has never been the problem. The problem is that the information is not getting through, for whatever reason, to some women on the ground.

Every time we in Epilepsy Ireland raise this issue we get two reactions. One is to ask if we will ever stop talking about it as people feel they already know about it. The other is from upset individuals like those who, following the "Prime Time" programme last year, could not sleep because they had never heard of the issue. The Organisation for Anti-Convulsant Syndrome did a survey of 100 pharmacies last year and found that less than 20% were even aware of the existence of the pharmacy card. It is not a question of doing things but of monitoring what is being done and the impact on the ground. We need to know that we will not be back here in two or three years' time having the same conversation. From the point of view of FACS Forum and Epilepsy Ireland, that is one of the critical questions.

The pharmacy regulator has set specific expectations for pharmacies. There is a mixture of trust and enforcement and all parties, including the HPRA and the HSE, need to be really clear about what they are going to do if we are still reporting medications going out in bags in six months' time, or the fact that 20% of women are still not aware of this.

Deputy Louise O'Reilly: I had asked a question on what penalties there were, if any. It is clear that there are none and that these are just recommendations. There is no possibility of enforcement and we are relying on people who are very busy to implement this. It is clear that it is not being implemented in all cases and that is worrying. The epilepsy in pregnancy register was raised. Can Mr. McGrane, speaking specifically for the HSE, say if it is possible that it can be adapted to take account of historical cases, as well as being used for the future? I appreciate that it may not be always possible to give a 100% diagnosis but if a mother has taken Epilim during pregnancy and has a child with some or all the symptoms as described, would it not make sense to assess the problem in a realistic way and assess its extent? There is a significant difference in the figures, that is, between 400 and 43, and if there was more openness on the part of the HSE to accept there might be an issue, it would be an awful lot easier to deal with it.

Do the witnesses think the register can be adapted to deal with cases retrospectively? If it can, when will it be done? If not, will a register be established separate to that?

Chairman: We are under a bit of pressure for time. I will bring in Deputies O'Connell and Donnelly and return to the witnesses for answers to those questions.

Deputy Kate O'Connell: The evidence of today is that there have been deficiencies in how this was handled, whether in Ireland or in the EU. It seems to have accelerated in recent years, ending up with a contraindication of the product in pregnancy. It is clear that there has been an issue with the dissemination of information, from EMA level down to real-life people, meaning people on the medication were not aware of the issue. I refer to the recent 20% figure to that effect coming from the UK. What are the HPRA and the Department going to do to ensure it does not happen again that such a thing takes so long to be felt on the ground? Many community pharmacists have an area for information and it is their responsibility, along with

prescribing doctors, to get the information to people. There seems to be a deficit in the information getting to people who were on the medication and about to get pregnant or who had already had children.

The link with neural tube defects is quite interesting and my understanding is that the rate of neural tube defects is rising here more quickly than in any other European country, partially due to the lack of folic acid supplements in foods. Can the Department say what we are doing about that? We have brought it up many times in this committee, both in connection with the eighth amendment and the national maternity strategy.

I am not making any correlation between thalidomide and this product but after the thalidomide cases there was an overhaul in how we assessed medication. Can the HPRA comment on the risks associated with not continually reassessing the safety of drugs and with licensing a drug for use without sufficient evidence to support its clinical safety? What are the risks of a rush to approval of a particular medication without knowledge of its long-term effects on pregnancy and babies? We might think a central nervous system, CNS, drug would not have an effect on developing life but clearly it does. This committee has recently heard of moves to license drugs without the appropriate safety information.

Where does the responsibility of the drug company lie in respect of this? This drug is off patent and it is very cheap now but it was very expensive 15 years ago. Time passes quickly. Where does the drug company's responsibility lie? What if Sanofi just decided for market reasons or because it was too much hassle to withdraw the drug from the market? How can the State encourage it to live up to its responsibilities?

Deputy Stephen S. Donnelly: I return to the parents' requests. I address my questions to Mr. McGrane. I heard three main requests. One was for a study on the children affected. We have debated that at some length and it sounds like progress can be made. The second request was for an investigation to be launched. Mr. McGrane may have indicated that that has been requested but it sounded more like a clinical conversation. Is an investigation into what has happened being launched, as has been requested?

My next question is on services. We have heard the parents' voices: "Never a month goes by without hospital or specialist appointments"; "I had to resign in 2016"; "Last December my daughter wanted to end her life"; "I have been stuck in a vicious cycle of guilt"; "The constant battling for services". It is clear that these parents are in a desperate situation and they should not be battling for services. The budgetary implications of helping them are tiny relative to the apparatus of the State. This is for a very small number of people and they are being spread all over the place.

Are the HSE and the Department acting as a matter of urgency to help these parents and their children? If so, critically, when will the parents and their children see a difference in their lives in terms of the battles they are having on behalf of their children?

Chairman: I will ask the witnesses from the HSE to speak first after which we will hear from the representatives of the HPRA.

Mr. Kilian McGrane: I will start with Deputy O'Reilly's question about the register. I cannot answer specifically as to whether the register in Beaumont can be modified. Perhaps Ms Flynn can comment.

Ms Cora Flynn: I was involved in setting that up with Professor Delanty in 2000. The Irish

data pools in to the British data with Jim Morrow and John Craig in the Royal group of hospitals. It prospectively gathers information on women when they become pregnant with what medications they are on. It monitors them through their pregnancy and then three months after the baby is born, the outcome of the birth is collected. It stops at that point.

It collects information on all antiepileptic drugs, not just valproate. However, the reporting of it is not mandatory - it is by clinician perspective. It depends on whether that woman is engaging in a specialist service. GPs can also register the pregnancy. It is currently funded by pharma.

Mr. Kilian McGrane: The issue is that we would need to see whether that register can be adjusted and what is technically required to put in the retrospective aspects of it. The broader issue is that the Minister has requested the HSE's clinical specialists to meet with FACS. Within that, one of the first things we have to do is quantify the scale of the challenge faced by families. That means we need some database of people affected.

This flows neatly into Deputy Donnelly's question about the range of services. We need to quantify the scale of the challenges in order to map out the service pathways and identify the associated costs. I appreciate it is small in a total budgetary context. However, if there are 400 families with complex multidisciplinary needs, we need to make a budget provision for that. The budget provision would also need to include a register if we are to establish one. It is a fairly significant piece of work. The first phase is that we get the right clinical experts to meet with FACS to ensure we have a full understanding of the breadth of challenges they face. We can quantify the scale of the problem and then put together the plan for how we resource this prospectively. Obviously the issues retrospectively are separate and I think they have been discussed at this stage.

Deputy Stephen S. Donnelly: On the plan, I imagine parents have a fear that while this important work goes on, nothing might be seen on the ground for months or even years. Can Mr. McGrane give any reassurance to the parents as to when they might expect to see service provision to their children?

Mr. Kilian McGrane: It is very difficult to quantify a timeline in this context because we do not know the scale of the problem. We know it is a very significant issue for a significant number of families. Once we get people together we can start to do that. I hope some things can be done before a separate budget allocation can be provided. I do not want to make a commitment to something we cannot honour until we know the scale of the problem. I appreciate that is very disappointing for the families, but they have engaged already. They are part of the HSE's response team that has been meeting since late last year.

The Deputy raised the issue of the investigation. I am not quite sure as to what an investigation would entail. I do not know what role the HPRA would have. A number of questions were asked on timing, such as when this was contraindicated in a way that it should no longer be used. Obviously we would need to have other neurology experts advising on the occasions when it should be used, at which point we are into a different territory. That is subject to further discussion. I certainly could not make a commitment on it today. I can understand why families would want to know why this has gone on for as long as it has. It is entirely reasonable.

Dr. John Murphy: Based on the contacts we have had from Dr. Colm Henry in the HSE we have arranged an initial meeting on 10 May to meet members of the parents group to discuss where we are with the issues. Obviously we take a lead from them because they have children

who are affected and we do not quite know where they fit into the system at the moment. We do not know how robust and clear their diagnosis has been. We do not know what the gap in their services is and what they require. We need to build it up. We will have an initial meeting on 10 May. We will not be slow; we will move fast on this. It is an important issue for the families.

Ms Cora Flynn: The difficulty is being brought from a GP to a paediatrician to then a paediatric neurologist and onwards to an adult neurologist. They find that very fragmented. Once there is a suspicion and if these cases can be identified and triaged urgently onto a pathway that is specifically resourced for them, I believe that will meet their needs. They have a wait to get to the paediatrician, a wait for the paediatric neurologist and perhaps another wait for the adult neurologist. That is where the time lag is. In the meantime the person needs services. That fragmentation needs to be leaner and those identified triaged and resourced.

Dr. Peter McKenna: The three issues Deputy Donnelly raised are legacy and historical ones. We in the women and infants health programme have as an aspiration that women with epilepsy would be seen at specialist clinics where there could be liaison between obstetric services and neurology services. This is difficult to achieve in all but the biggest hospitals at the moment owing to the scarcity of neurologists. There are very few in the country and their services are spread very thinly. That would be one of our aspirations.

Another one would be that women who attend these clinics would have access to specialist scanning with targeted anomaly scanning so that if possible, the problem could be diagnosed at an early stage should there be an anatomical problem. The third is that they could be put in contact with paediatric services upon discharge so that if there was any developmental problem, they could access remedial services as soon as possible. The aspiration of those in the women and infants health programme would be to deal not just with the valproate issue but with women who need specialist epilepsy services.

Chairman: I will call speakers from the HPRA and then come back to the witnesses from FACS. I call Dr. Gilvarry.

Dr. Joan Gilvarry: I will let Dr. Spooner start with some of the questions.

Dr. Almath Spooner: The two main questions addressed to us were from Deputy O'Connell. My understanding is that there were two main pillars to those. One was on the risk minimisation. Communication does not seem to have been optimally delivered and the Deputy asked what we are doing differently now. We are making it a requirement of the licence that these things are done. I refer to any failure to provide patient cards or failure to provide precise information on the magnitude of the risk. Use of the medicine in a woman of childbearing potential who is not on effective contraception will be off licence now. That is a change.

In terms of the enablers, we are putting a formal pregnancy prevention programme in place. That is recognising that there have been deficiencies associated with a lack of clarity on different roles and responsibilities around the patient journey. What is the role of the regulator, the specialist, the general practitioner and the community pharmacist? What are the clinical enablers that allow steps to be taken at the appropriate time in terms of decisions on therapeutic options but also information provision? The new recommendations and the new clarity on the licence, supported by what will be a pregnancy prevention programme that will be branded "Prevent" and that will have a suite of measures that have been fully informed by engagement with patients and health professionals, will be a very substantial change and a framework around risk communication as opposed to *ad hoc* bulletins and the like. We have to recognise that we are

doing this for this medicine because of the magnitude of the risk, which is not neutral in terms of burden. This is a medicine a woman will be on for a long period of her life and the risk of pregnancy will vary, so it needs to be adapted to the woman's individual circumstances.

In terms of moving forward, we have a more robust approach now to communication, at least from the perspective of what we are accountable for, which is the regulation of the product.

On the question about the other pillar of risk management, which is around evidence generation and how we research medicines at a population level when we have uncertainties, linked to that is the availability of electronic resources, electronic health records, and having the possibility to research population use of medicines. In terms of much of the pharmaco-epidemiological research, we have had a lot of discussion on the complexity around interpreting individual cases but we have had studies which can get around many of those issues with sophisticated data linkage. That is not always possible for every medicine but what is clear now is that for every medicine we have a risk management plan and at the time of initial authorisation we ask about the uncertainties and we plan proactively to reduce those uncertainties. If sodium valproate was being put on the market today, having seen the non-clinical data and having the concerns about physical defects, we would be requiring the company to do pharmaco-epidemiological studies.

I hope I can provide some reassurance that, going forward, lessons have been learned. We have a much more robust approach to the vigilance of medicines in pregnancy. Perhaps the thinking in the past was that we cannot research medicines that are used by women who are likely to become pregnant. There was a reluctance to research. That has evolved. We understand that women will be treated for chronic conditions. They will want to plan pregnancies and they need reliable and complete information on the relative harms for different medicines in pregnancy. As regulators, we are accelerating efforts, a term used by Deputy O'Connell, and that is a fair reflection. As part of that, and I do not want to get into regulatory speak, in the next year at the Pharmacovigilence Risk Assessment Committee, PRAC, as well as having the research we are doing at national level, we will be developing a good vigilance practice guideline that will be binding on the marketing authorisation holders. That will be taken into account in all of the risk management plans and the planning of studies to reduce uncertainty so that we do not see these kinds of issues arise in the future with such a time lapse before we get complete and accurate information on the magnitude of the risk. I hope that answers the question but if I have overlooked anything, please remind me.

Chairman: Thank you very much, Dr. Spooner. I might give the final word to Ms Joan O'Donnell.

Ms Joan O'Donnell: Does Mr. Murphy want to say something first?

Senator Colm Burke: Chairman, I asked a specific question about the systems in place with regard to medications that are available for a long period of time and I am not clear if it was answered.

Dr. Joan Gilvarry: I will come in on that. Somebody said there was a rush to approval of products. There is never a rush to approval of products. They must meet pre-specified quality, safety and efficacy data and that is continually monitored throughout the life cycle of that product. We get periodic safety update reports from the company. We continually monitor adverse reaction reports and detect signals through the European database. If there is a red alert, as the Senator calls it, it can be referred immediately by us or any other member state to the European committee for a full scientific review. That is what happened here.

As Mr. Murphy said, we have extensively and repeatedly communicated on the product to healthcare professionals in recent years and the problem is that the message is not getting through. We regulate the product. We recently asked the HSE, the clinical leads and the lead in primary care to come in to us to see how they can help us get the message through to the GPs via the neurologists, to the prescribers via the psychiatrists, and also to the pharmacists via the Pharmaceutical Society of Ireland, PSI, which was represented at that meeting. We are not in the doctor's surgery when the doctor is prescribing and talking to the patient. We are not in the pharmacists when the medicine is being dispensed, but all of these are trying to assist us now. The PSI recently sent communications to other pharmacists to make sure the package leaflet and the patient alert card is given at the time of dispensing, and the head of primary care has written to all the GPs to tell them they need to identify the patients who are on this treatment at this time. They are following up, which is very good and I appreciate it, with the GPs in terms of identifying the patients who are women of childbearing age whom they have on this medicine.

We need help to implement all our recommendations. We cannot do them alone. We need the pharmacists, the HSE, the neurologists, the GPs, the psychiatrists and everybody in the healthcare system to listen and implement what we have been saying for years.

Ms Joan O'Donnell: I will say a few words and then hand over to Mr. Murphy. We appreciate all the areas covered. The role of the State and how we deal with the legacy issues is still outstanding. We would like the opportunity to return to that issue.

The speakers from the HSE and the Health Products Regulatory Authority, HPRA, spoke about the unintended consequences of taking people off medications early, etc. The unintended consequences of not dealing with this issue now will be devastating. They have been devastating for people so far. The first person with a diagnosis of foetal anti-convulsant syndrome, FACS, in Ireland was born in 1987. Unfortunately, we are fairly sure there are children born in Ireland who are living with this condition today. That is what we are dealing with and it is the reason we are here. What is the role of the State in this and where does accountability lie? Those questions are still outstanding after this.

We very much welcome and look forward to seeing the initiatives outlined by the HSE and, in terms of when we knew about the products, the time lags between when information leaflets were changed in the United Kingdom versus Ireland. That is my final comment.

Mr. Peter Murphy: Deputy Donnelly asked about the calls for an investigation. I would highlight that when we met the Minister, he committed to reply to us on that specific issue by the end of May. We look forward to his response on that. He wanted to address the issue with his team and his officials internally, and he has promised to come back to us very soon.

In essence, we have three questions on that investigation. First, what happened in the past across the entire system? Second, why did it happen? Third, what can we learn from it? That is an investigation worth having, not just for the parents involved and the people who are affected today but learning for the future in terms of other medications, groups or parents who might well be here in ten years.

On the service needs, we have to remember that the first step in putting any plans in place for service provision will start with a diagnosis. The very first question that needs to be addressed in the entire area is how we will address diagnosis of potentially hundreds of cases in a service where, in the national centre for genetics, we have four consultant geneticists, ten

counsellors and a waiting list of more than 1,300 people, including about 400 who have been on the list for more than 18 months. It is clear that the national genetic strategy must be funded, resourced and started. There has been much debate on that issue and I presume it has been discussed by the committee.

Another service issue mandated by the new European guidelines, and the pregnancy prevention plan in particular, is that all women taking this drug must have an annual review by a specialist rather than a general practitioner, GP. The question of how we will fit 500 or 1,000 women newly diagnosed with epilepsy into the specialist neurology service in Ireland in the current situation whereby it is already under-resourced remains outstanding and has not been addressed in detail today. There are 34 neurologists nationwide but there should be double that number according to minimum guidelines from the British Association of Neurology. There is a resourcing issue in that regard. The reviews must be carried out but we must ask how that will be done in practice when we have so few resources, including consultant neurologists, epilepsy specialist nurses, etc., to handle this scenario.

Deputy Louise O'Reilly: As Mr. McGrane indicated that the Minister has advised that matters are to be put in train, I suggest that the committee reconvene in a number of months to get a progress report and an update. It would be helpful if anything of relevance were communicated to us in writing in the intervening time.

Chairman: The committee will meet in private session to consider the evidence that has been given and our response. A transcript of the meeting will be sent to the Minister. On behalf of the foetal anti-convulsant syndrome, FACS, forum, the Health Products Regulatory Authority, HPRA and the Health Service Executive, HSE, I thank the witnesses for giving evidence this morning.

Sitting suspended at 11.32 a.m. and resumed at 11.44 a.m.

Council Directive 2013/59/EURATOM: Discussion

Chairman: In this second session we are meeting representatives of the Chiropractic Association of Ireland, CAI, to discuss the impact on chiropractors of the transposition of Council Directive 2013/59/EURATOM laying down basic standards for protection against the dangers arising from the exposure of ionised radiation. On behalf of the committee, I welcome Mr. Tony Accardi, Ms Lyndsey O'Leary, Mr. James Cosgrave and Mr. Richard Brown of the Chiropractic Association of Ireland.

I draw attention to the fact that 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. If they are directed by the committee to cease giving evidence on a particular matter and they continue to so do in respect of a particular matter, they are entitled thereafter only to a qualified privilege in respect of their evidence. They 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, persons or entity by name or in such a way as to make him, her or it identifiable.

I also wish to advise that any opening statements made to the committee may be published on the committee's website after this 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 invite Mr. Tony Accardi of the Chiropractic Association of Ireland to make his opening statement.

Mr. Tony Accardi: As president of the Chiropractic Association of Ireland I thank the members of the Oireachtas Joint Committee on Health for agreeing to meet us today. While our requests are technically complex, the principle is simple. These regulations, as currently drafted, will place the delivery of evidence-based, patient-centred chiropractic care in Ireland at a serious disadvantage. They will remove the capacity of duly qualified chiropractors to conduct X-ray examinations of patients or to refer patients for X-ray. This regulatory change will have a profoundly negative impact on the safe and competent delivery of care that chiropractors provide to thousands of Irish patients each year. I hand over to my colleague, Mr. James Cosgrave, to explain briefly who we are and what we do.

Mr. James Cosgrave: I am a chiropractor practising in Cork for the past 25 years. Chiropractors specialise in the assessment, treatment and management of musculoskeletal disorders, particularly those affecting the spine and related joints. The World Health Organization, WHO, recognises chiropractors as primary healthcare providers, safe to practice competently either independently or as part of healthcare teams at a community level. Chiropractic is statutorily regulated in more than 50 countries around the world. Ireland remains the only English-speaking country in the world that still has no statutory regulation of chiropractors.

The Chiropractic Association of Ireland is the professional association that represents chiropractors and maintains professional standards in the absence of this statutory regulation. The CAI has 110 members working in private clinics nationwide who deliver more than 600,000 treatments per year to patients with musculoskeletal conditions. This a significant treatment volume and it is delivered at no cost to the State. To deliver this level of care effectively, chiropractors require prompt, efficient and well-regulated access to appropriate diagnostic imaging when required. The European Commission has published training requirements for chiropractors to justify, deliver and refer for X-ray procedures. Without exception, our members are meeting these requirements. As part of their five-year, full-time education, chiropractors are trained in the safe and effective use of X-rays and have done so for many years.

In Ireland, chiropractors have been able to refer patients for X-ray for more than 25 years and a number of our members have also had X-ray apparatus in their clinics licensed by the Environmental Protection Authority, EPA, and previously by the Radiological Protection Institute of Ireland, RPII. One member, as far back as 1991, was licensed by the Nuclear Energy Board. We have sought regulation of X-ray by chiropractors for more than 20 years. Members of this committee might be surprised to learn that I made a presentation to an Oireachtas joint committee in 1999 on this very issue of X-ray use by chiropractors. The record shows that the Chairman of the committee at the time, the late Deputy Sean Doherty, advised that the parties should engage further to resolve the situation ahead of the, at that time, upcoming new regulations. There are a lot of similarities to the situation we are in 19 years later.

There was a period of significant activity around the 2002 regulations. The Department of Health did undertake to create a register of chiropractors who could take and refer for X-rays. The CAI fully participated in this process throughout 2003. Progress was going well but it stopped completely in 2004 for an unrelated reason. There was a consultants' dispute at the time. The Department was in dispute with the Irish Hospital Consultants Association over a medical indemnity issue. As a result, the consultants pulled out of any health committees. One

of those was the medical exposures directive advisory group, MEDAG. Therefore, the work of creating the register of chiropractors competent to take X-rays and refer for X-ray was never finished. There was no question at the time that the competencies could not be met. It was simply that the work was never finished. We have a very long paper trail, stretching from 2004 to 2006, from the then principal officer in the Department stating the reason for the delay in creating the register was, in fact, the consultants' dispute and nothing to do with chiropractors' competencies or willingness to engage on this.

The correspondence deserves scrutiny because it gives a very clear indication that the Department gave an undertaking, at the start of the process, of regulating chiropractors under these regulations. Since the time in question, it has been stated that since we are not part of the 2002 regulations, we should not be included in the 2018 regulations but, in fact, the Department has given an undertaking to include us under the 2002 regulations. Nonetheless, during this entire period, chiropractors have had continued access to private X-ray facilities around the country run by Irish Medical Council consultant radiologists. Further, some 11 chiropractors have continued to operate their own X-ray facilities, licensed by the RPII or the EPA, in full compliance with SI 125. These chiropractors participated in a HSE compliance audit in 2012. It is important to point out again that while the 2002 regulations do not specify chiropractors as practitioners, the HSE nonetheless conducted this audit of chiropractors on the basis that they were, in fact, acting in the role of practitioners and had been doing so for many years.

The audit findings were very good. They stated very clearly that it is encouraging to note that chiropractors have taken steps to implement quality assurance and safety mechanisms, and that virtually all practices have written protocols with regard to safety, justification and optimisation. The CAI has endeavoured to self-regulate any gaps left by the absence of the register that was promised in 2002. We still continue to seek full participation in the relevant statutory structures rather than engaging in self-regulation. The new regulations, to be signed by the Minister, Deputy Harris, in the coming weeks neglect to include chiropractors under their remit altogether, even though the European guidelines on the training of medical practitioners to carry out these roles make it very clear that chiropractors meet the standards required - in the EURATOM directive and the transposition regulations. We met Department officials in February and had an exchange of views but we are unaware of any progress made on this to date. As a result, chiropractors now face being unable to refer for X-ray or take an X-ray for the first time in over 25 years. The Department is fully aware that the equivalent new regulations in the United Kingdom do specify chiropractors are fully competent to take and refer for X-rays, so it is widely understood that the competencies required for chiropractors in Ireland to carry out the same roles are not the issue.

At this time, we are not seeking any additional rights over and above what was agreed by the Department in 2002. We are asking for our use of X-ray to be regulated, as we have always done. We fully endorse the Department's desire to have proper regulation in the area. We still stand ready to engage on any practical solutions the Department might suggest to resolve matters. We fully support the statutory imposition of minimum training standards and of required clinical governance and auditing.

I shall now hand over to my colleague Mr. Richard Brown, from the World Federation of Chiropractors. He will explain the international context.

Mr. Richard Brown: I thank the Chairman and members of the committee for permitting me to address them briefly today on the international perspective as it relates to this issue. The World Federation of Chiropractic, WFC, is the global voice of the chiropractic profession. We

represent the national associations of chiropractors in over 90 countries, spread across seven world regions. Our role is to advance the chiropractic profession and to promote high standards of education, conduct and practice.

Members will have heard that there are some 110 chiropractors in the CAI. Members may regard the profession as small but, in a global context, they will note there are upwards of 110,000 chiropractors in the world today. Most of these are clinicians caring for patients and their communities. Others are researchers, academics, health policy experts or public health advocates. Chiropractic, therefore, is an established, respected and valued global healthcare profession.

Since 1997, the WFC has been an NGO in official relations with the World Health Organization, WHO. As members already heard, the WHO recognises chiropractic as a primary contact healthcare profession. Back in 2005, the WHO published guidelines on basic training and safety in chiropractic. These guidelines clearly set out the requirements of chiropractic educational programs, which include training on radiation protection, radiography and radiology. They set out practical training in the taking of X-rays and interpretation of X-rays. It should, therefore, come as no surprise that the safe and effective use of ionising radiation in the form of X-rays is a core component of every single chiropractic training programme around the world.

Quite rightly, members will all wish to be satisfied as to the quality of education of chiropractors. As they have already heard, chiropractors undergo a minimum of four years' full-time education at masters level. Thousands of hours of basic science and clinical sciences training form the curriculum, and competency is tested at every stage. Upon graduation, chiropractors engage in continuous professional development, quality improvement measures and auditing of their work.

Chiropractic is offered at over 40 educational institutions worldwide. Three of these programmes are in the United Kingdom, namely, at AECC University College, the University of South Wales and BPP University. A fourth, at London South Bank University, will open its doors later this year. These programmes are both nationally and internationally accredited, ensuring quality assurance at a number of levels.

Let us return to the issue of X-rays, a critical component of effective and accurate diagnosis. In the world today, over 85% of practising chiropractors exercise their competency in taking X-rays, interpreting X-ray films and referring for diagnostic imaging, including X-rays. Chiropractors in every one of the 50 states in the United States, every province in Canada, every territory in Australia, and in England, Scotland, Wales and Northern Ireland are entitled to take, read and order X-rays. They take the role of employer, practitioner, operator and referer.

In the United Kingdom specifically, a 2006 multi-stakeholder document, Clinical Imaging Requests from Non-Medically Qualified Professionals, contained the policy statement from the Society and College of Radiographers. It stated it is perfectly in order for radiographers to accept requests from non-medically qualified referers provided the referer is adequately trained and remains competent to refer, and provided that there are written local agreements and protocols. In the same document, the General Chiropractic Council, which is the regulator, stated chiropractors are autonomous primary healthcare practitioners competent to provide diagnostic triage. The majority are fully trained to take as well as interpret images and interpret reports from radiologists. It is stated that when requesting imaging protocols they will provide a clear diagnostic rationale based on a well-founded clinical impression.

Back pain is the single biggest cause of disability on the planet. Chiropractors manage musculoskeletal disorders, including back and neck pain, at all stages of the life course. Their judicious use of X-rays plays an important role in directing safe, effective care.

My colleagues around the world, not least those in the United Kingdom, United States, Canada and Australia, many of whom trained alongside CAI chiropractors, are shaking their heads in dismay over the prospect of Ireland seeking to prohibit chiropractors, as highly trained skilled health professionals, from exercising their scope of practice and competency. The WFC respectfully submits that to do so cannot be in the best interest of either patients or the public.

Mr. Tony Accardi: I thank the committee once again for affording us the opportunity to present our case today. My colleagues, whom members have met, in addition to Ms Lyndsey O'Leary and Ms Olivia O'Leary Veal, who are X-ray licence holders, are willing to take questions at this time.

Chairman: I thank the delegates for the opening statements. We will now hear observations from members. The first to contribute are Senator Colm Burke and Deputy Louise O'Reilly.

Senator Colm Burke: I thank the delegates for their very comprehensive presentation on the work they are doing.

With regard to the services currently being provided, the delegates said some chiropractors use their own X-ray equipment and others make referrals.

Could I get clarification on medical indemnity insurance? Does each practising chiropractor have professional indemnity insurance? In particular, do those who are doing extras and giving reports have professional indemnity insurance? Will the witnesses outline the number of people in total who are practising chiropractors in this country? What is the number in real terms? Will the witnesses explain the number who have and use X-ray equipment? The issue arises that if people do not have X-ray equipment, to whom would they normally refer people? Would they refer people to hospitals or private providers of X-rays? I ask about professional indemnity insurance because I came across a person providing an X-ray service but when an issue arose, it turned out the person did not have that professional indemnity insurance. I am not talking about a chiropractor in this case, just in case anybody is worried about it. An error was made in the case I mention and it is a major issue. I have been very involved in legislation relating to this in the past four or five years to ensure all healthcare professionals have insurance. It should be clarified.

I presume the amendment of the proposed regulations would be quite minor in order to include chiropractors. It is not a case of drafting new regulations but rather including rather than excluding chiropractors. I thank the witnesses for the presentation.

Deputy Louise O'Reilly: I thank the witnesses for their evidence. I have two questions, with one relating to a submission we have not yet heard. It relates to the training. We will hear from radiologists that "when compared with the trained and regulated health care professionals previously described, we have found no substantive evidence of appropriate training, referral criteria, audit or accountability". Will the witnesses outline for us their training levels and how they compare with training levels in the North or England, where this practice is allowed? Do they do something different 50 or 60 miles up the road that people are not doing here? It would be helpful to explain that for us so we can understand the process.

If the Department continues on the path it has indicated and chiropractors are not brought

into the process, what practical effect will it have on work and the ability of witnesses to carry out their work? The comments on going back to 1999 are interesting. Is it correct to say that between 1999 and today, the practice has continued without any adverse occurrences? Is there a reason we should be concerned? It strikes me that in 1999 the association was willing to engage with regard to regulations and satisfying the criteria that might be put in place. I assume the state of play is still the same and the association is still happy to engage on this. In the discussions with the Department, has there been an indication of any minimum standards that should be fulfilled that the association is not currently fulfilling? Has the association been advised of anything not being done that the Department would like it to do?

Chairman: If the witnesses bank those questions, I will bring in Deputies Durkan and O'Connell in order to complete contributions from members.

Deputy Bernard J. Durkan: I have stated my interest in this area from the outset. I am totally supportive of the need to retain X-ray facilities for chiropractors. I say this because there is an obvious need to keep the highest possible standards and to have qualifications of international repute. The degree of training must be observed and updated in line with international standards. Safety regulations must apply with X-rays at all times. I strongly urge that in all cases, high standards must apply and there must be a level playing pitch.

As the Chairman knows, I have on many times in the past criticised the existence of waiting lists for virtually everything in the country but particularly in the health service. One does not have to wait very long for an X-ray by a chiropractor, which is very beneficial for the patient. Nobody else seems to worry about such things but the patient is most concerned about that. A patient can go to a chiropractor and have an X-ray and result within ten minutes. That does not happen in most other places. It could and probably should happen but it does not. I, therefore, strongly support an effort to ensure the full degree of services already available through chiropractors continue to be made available, including X-rays. This can happen if the adequate qualifications apply to ensure patient and practitioner safety with regard to ionising radiation.

Deputy Kate O'Connell: I thank the witnesses for coming in today and I apologise for them being delayed for so long this morning. The quote mentioned by Deputy O'Reilly was something I pulled from the statement last night as well when I read it. It is "we have found no substantive evidence of appropriate training, referral criteria, audit or accountability in published literature from the Irish chiropractic community." Reading around this, it almost suggests that there is no evidence. Perhaps the evidence is there but it just was not collated or given in the appropriate fashion.

Why is Ireland so different from other jurisdictions? I can only assume it is because there is no undergraduate university course for chiropractic services, so perhaps the profession does not have what pharmacists or physiotherapists have in the form of an academic body in Ireland providing the degree course. Therefore, we depend on people coming in with training from other jurisdictions. I completely understand concerns that people may have with ionising radiation X-ray units in clinics but I wonder is there any evidence that those units are not being monitored and manned properly, or that there is any risk to the neighbourhoods surrounding practices with such facilities? Will the witnesses indicate how many patients the group is seeing on a weekly or annual basis? They might deem this as taking a weight from the health service by dealing with them in their centres. I visited a chiropractic clinic recently and was very impressed by the professionalism of the set-up. It was what I would consider very progressive and like a large GP surgery. It was not just a fly-by-night operation and the person had practised for years. Following on from the point on indemnity insurance to which my colleague, Senator Burke,

referred, and he was referring to the actual machines, when it comes to something being missed, as can happen in any profession, what is the recourse for the patient? If an X-ray is taken of a lower back and if the issue is not mechanical but is, for example, cancer and that is missed, is there any example of what happens next? How is it regulated? Is there any regulation? Does it just go into the ether?

I looked at the regulations for here and the proposed regulations for the UK and I am concerned that we seem to be an outlier. Why can Ireland not match up with what the UK is doing? Do the witnesses have any suggestions as to how they, as a group, could get their house in order? They appear to be well trained and providing a good service, but somehow they operate in a grey area and perhaps will become extinct. Do they have any suggestions as to how, if we as a committee could feed back to the Minister to give the witnesses two or three years to sort out their housekeeping, they could assist us in this regard?

Chairman: Before the witnesses start answering those questions, perhaps they might refer to the definitions of practitioner and referrer because they seem to be central to the issue with regard to being a practitioner who is entitled to refer for X-rays. As has been mentioned, in 2002 the Department undertook to include chiropractors in the regulation, but 16 years later this has not happened. Perhaps the witnesses will explain how that could have happened. Is there statutory regulation for chiropractors in the other countries that have been mentioned? Is Ireland different from other countries in that it does not have a process for statutory regulation? Are chiropractors acting as radiologists and radiographers in the process of taking X-rays, or are they referrer, radiographer and radiologist in the process at present, whereby some chiropractors have access to X-ray facilities?

We have had a lot of questions from five different members but perhaps the witnesses will take them as they wish.

Deputy Bernard J. Durkan: I omitted dentists from people who carry out X-rays. They do it very well and I want to include them.

Mr. Tony Accardi: Mr. Cosgrave will comment on the practitioner and referrer definitions.

Mr. James Cosgrave: Must I answer the questions in sequence?

Chairman: No.

Mr. James Cosgrave: I thank Deputy O'Connell for her questions. We have never asked to be self-regulating. We have asked to be within the regulatory remit of this new statutory instrument and the existing one, SI 478/2002. We have been left outside this. We have consistently asked to be included and to be regulated and held accountable. It is very straightforward. If we are included in the regulations our members will be held accountable. Either they are able to perform the tasks as required by statute or they are not, but it does provide a mechanism for the relevant authority, in this case HIQA, to remove anybody who is not able to operate their duties in a responsible fashion. We feel the lack of statutory regulation of chiropractors' use of X-ray is absolutely undesirable. We have been on the record for more than 20 years as seeking to be involved under the statutory remit of the appropriate regulations.

On the question regarding the use of X-ray apparatus by chiropractors, they are acting as referrer and practitioner, much in the same way as dentists and it is quite routine in dental practice. Chiropractors are trained to interpret the films from a diagnostic perspective, but in most cases radiology reports will also be provided from outside sources.

On the insurance front, it is a compulsory requirement for all members of the Chiropractic Association of Ireland to hold malpractice insurance and insurance that will cover any eventuality. Any of our members using X-ray apparatus is covered under the appropriate insurance. There has never been an issue arising with regard to insurance and X-ray use by any of our members. There are 130 chiropractors in the country, 110 of whom are members of our association, which is approximately 85%, and a total of 11 chiropractors in the State are licensed to have X-ray apparatus. This means 99 chiropractors do not have X-ray apparatus and they have been making referrals to private diagnostic clinics throughout the country. These include the Consultants Private Clinic in Cork and there is also a large private provider of X-ray and MRI services in the State. We have access to refer our patients to these facilities.

Regulation 14.4 caters for people who are not specified as referrers, and at this point in time I am not specified under SI 478 as a prescriber, as it allows for the radiologist in charge to act as the referrer and receive the referral in the event of a referral being made by somebody like me, who is not listed under the current regulations. This situation has worked incredibly well for the past 16 years. I have been referring patients to Irish Medical Council consultant radiologists in the State for 25 years. I have been receiving reports back from those radiologists, and it has been a fantastic service and access has been great. We also have the backup and security of a consultant radiologist's report. This has been working very well, hence the number of X-ray licences issued to chiropractors throughout the country has actually decreased from the 18 licences issued a few years ago to 11 now because there has been good private access and many of our members have utilised this.

Things will change after the introduction of the new regulations, if they remain unamended. I will no longer have the ability to refer to a member of the faculty of radiologists here to have an examination done on a patient. Instead, I will have to refer the patient back to his or her GP and, obviously, provide all of the clinical information as to why I feel the X-ray would be justified, and the GP may or may not make the referral. It means every patient will have to take an extra step. It will delay things and slow them down. Some patients will end up in the public system again and will congest things further. The new president of the National Association of General Practitioners recently said patients could soon wait up to six weeks for a GP appointment, which is curious. It seems very much in contrast to some of the Sláintecare recommendations, on which members of the committee worked tirelessly, to slow down access to diagnostic imaging and delay things. Chiropractors have been working with these arrangements for many years and it has worked very efficiently to the patients' benefit. We are not talking about a huge number of X-rays per year. We have approximately 600,000 visits per year and we certainly refer a very small percentage of patients for X-ray. It is thought that at present chiropractors take 3,000 to 4,000 X-rays per year, which is hugely at variance with the 1.5 million to 2 million X-rays being taken by other providers in the State. We are not talking about a huge number of X-rays but, nonetheless, when an X-ray is required and used it is a very important diagnostic tool to which we must have access. This change will completely remove access to that diagnostic tool for chiropractors.

Chairman: Will Mr. Cosgrave distinguish between the various types of referrals required? X-ray is one and MRI and CAT scans are others. Is there a difference between them?

Mr. James Cosgrave: Typically we do not refer for CAT scans. Part of regulation 14.4 states the radiologist receiving the referral must be satisfied the study is required and necessary. No, the main referrals will be for simple lumbar spine or cervical spine or knee or hip X-ray. We tend to use a lot more MRI nowadays. Therefore, the amount of X-ray referral is actually

decreasing, not increasing, and I think this trend will continue. I can see in the foreseeable future that MRI will be much more readily available and utilised much more often. MRI does not involve ionising radiation. Nonetheless, the fact that chiropractors will potentially not be listed as referees under the new regulations could interrupt access for MRI referrals because the assumption is that the private facilities may well be unhappy to take referrals for MRI if chiropractors are locked outside these new regulations completely, even though MRI does not involve ionising radiation.

Mr. Tony Accardi: Deputy O'Reilly asked us to outline training levels, comparing Ireland to Northern Ireland and England. Perhaps Ms Olivia O'Leary Veal could take that question.

Ms Olivia O'Leary Veal: I might defer to Mr. Brown on the international level to draw the comparison between the UK-based and the Republic-based systems.

Mr. Richard Brown: I think one of the original questions was why is Ireland so different from other jurisdictions? It seems as though one of the barriers to regulation of the profession has centred around domestic chiropractic education and the need for a chiropractic educational institution in the country before regulation can be contemplated. I respectfully draw the attention of the committee to three other jurisdictions in Europe which are regulated but have no educational facility in the country. Most notably, Norway is a case in point. Norway has approximately 800 chiropractors. They have a wide scope of practice. They have wide practice rights, including the prescription of sick leave and referral to diagnostic imaging and to physiotherapy autonomously as a profession. They have used this facility very widely, and chiropracting is very well utilised.

Deputy Kate O'Connell: Can they take X-rays in Norway?

Mr. Richard Brown: They have referral rights for X-rays. Most chiropractors in Norway have a very easy facility to be able to refer into local facilities.

Deputy Kate O'Connell: However, fundamentally, Mr. Brown has drawn the comparison between Norway and here. Are chiropractors in Norway allowed to have X-ray units in their practices?

Mr. Richard Brown: No, they are not.

Deputy Kate O'Connell: It is not really a good comparison, then, with all due respect. Of the few countries, is there any other jurisdiction that has no school of chiropractors and in which chiropractors are allowed to take X-rays in their practices?

Mr. Richard Brown: That is unregulated or regulated?

Deputy Kate O'Connell: Mr. Brown referred to either three or four a minute ago that had no undergraduate chiropractic degree or whatever. In any of those cases, are they allowed to take X-rays in their private clinics?

Mr. Richard Brown: Autonomously, in Europe, the other two jurisdictions were Cyprus and Lichtenstein. Chiropractors there do not have the right to own X-ray equipment but they do have referral rights. Outside Europe, I refer to Australia, the US and Canada. Chiropractors there all have the right to own and operate X-ray facilities within their practices. When we consider the numbers of chiropractors globally, which I referred to, they represent approximately 85% of chiropractors in the world today within these jurisdictions.

Chairman: Is it the case that if one has the right of referral, one does not need X-ray facilities in one's practice?

Mr. James Cosgrave: It seems to be the case that there is much less of a likelihood that one would need one, given that 100 of our members do not hold X-ray apparatus. Some 10% do.

Chairman: Is it that the 10% that do do so because they do not have referral rights?

Mr. James Cosgrave: In some areas, yes. Some of those licenceholders are in rural areas.

Mr. Tony Accardi: There was a question about undergraduate programmes in Ireland. We are actively pursuing that. There is an organisation called Promoting Chiropractic Education that has been developed in England. It produced the groundwork for the London Southbank programme that Mr. Cosgrave mentioned. It will help us develop a programme in Ireland, and we are actively pursuing that, as I said. As a matter of fact, a number of years ago, an entire curriculum was developed for our programme, so we hope to have something up and running possibly in three or four years.

Deputy Kate O'Connell: If I may, Chairman, someone referred to the fact that 18 X-ray licences were issued to chiropractors a few years ago. There are 130 chiropractors in the country, 110 of whom are affiliated to the CAI. There were 18 who had X-ray machines and now there are 11. Is that due to the cost of maintaining such units or to the fact that the private operators with diagnostic stand-alone setups might be more efficient, or is there any other reason? Within the profession - of the 110 or the 130 or 140 - do chiropractors refer within their own practices? Would it be normal for a chiropractor without an X-ray machine to refer to a chiropractor who has one - in other words, no referral to the radiographer or the radiologist? Do referrals happen within the practice?

Mr. James Cosgrave: There is some inter-referral, absolutely, but such cases are very much in the minority. In most of the population centres where there is good access to private facilities, patients tend to be referred into those. As to the reason for the decrease in the number of licences, if I may backtrack again to 2002, we are talking about only three X-ray apparatus licensed to chiropractors at that time. It grew to 18 at one point. It has now decreased again to 11. X-ray apparatus is expensive. It is a facility that must be very well maintained, it is absolutely not cheap and, for many people starting practices, if there is a very good private provider run by radiologists in the locale that is willing to accept referrals when justified, that is a very good situation to have. There has been greater reliance on MRI in recent years as well, so many chiropractors now favour MRI. This trend will increase, although I do not see a time when X-ray will ever be obsolete as a diagnostic tool. It has been used by doctors and chiropractors for over 100 years and will continue to be so, although I think the numbers of chiropractors even seeking X-ray licences will come down. Under the new regulations, obviously, we might not even have that capacity.

Mr. Tony Accardi: Deputy O'Connell asked about any evidence of X-ray units not being monitored properly and whether the community is at risk. Perhaps Ms O'Leary might respond.

Ms Lyndsey O'Leary: X-ray licences are licensed from the Environmental Protection Agency, which basically regulates us. Every three years there is an inspection. We must have a radiation protection adviser, RPA. We have an Irish-registered radiation protection adviser who is also a hospital-based RPA. The licence is heavily regulated. There are many hoops to jump through. It costs money every year. One must have one's X-ray machine digitally inspected as

well, so the regulations are fairly extensive.

Ms Olivia O'Leary Veal: There are stringent procedures under SI 125/2000. There are many obligations on the licence holder to come to a standard that is accepted across all professions. The Environmental Protection Agency is the regulatory body and considered the competent authority in the area. There must be justification for the application for the licence initially and then one must satisfy the criteria yearly to satisfy an inspection report. Many of the chiropractic facilities within the State have been regularly inspected by the Environmental Protection Agency, and in this sense there is quite inherent regulation within the processes. One will not be passed for re-license throughout the following year if one does not submit one's reports under the radiation protection adviser who is there. There are therefore many checks within the processes in Ireland already. However, the status is not as we would like it to be. We do operate in rather a grey area, but we are doing our best to comply with the regulations and what is being demanded of us as a profession under the system under which we exist.

Mr. Tony Accardi: Deputy O'Connell asked about having our house in order. I reiterate that the Chiropractic Association of Ireland is very much in tune with self-regulation. We try to follow the Health and Social Care Professionals Act 2005. The Act requires professions to be regulated and among the main criteria are accountability and expertise. The association certainly has a significant proportion - 85% - of the practitioners in the chiropractic field. We have a written constitution and there is open democratic decision-making within the association. We have our codes of ethics and this is our robust fashion of disciplining any chiropractor who has breached those codes of conduct. We are also committed to continued professional development.

Deputy Louise O'Reilly: I think Deputy O'Connell was asking how long would it take for the Chiropractic Association of Ireland to be able to satisfy the Health and Social Care Professionals Act or other criteria. Mr. Accardi is essentially saying that there would not be a time lag. He is saying that if we were to speak to the Minister and advise him to give chiropractors a certain amount of time to get themselves up to speed, a huge amount of time would not be required.

Mr. Tony Accardi: No, we have everything in order.

Deputy Louise O'Reilly: Very well.

Mr. James Cosgrave: There was a question on the training requirements the Department has set out. In this case, the Department has not set out training requirements for us at all. The training requirements are set out in the EURATOM directive to be transposed. The European Commission published guidelines on what exactly chiropractors had to do and what level of training was required in 2014. Curiously, these guidelines were prepared by the European Society of Radiology, of which the Irish Faculty of Radiologists is a member society. The guidelines clearly state requirements for chiropractors referring for, justifying and delivering radiography procedures. At no point have we been looking for a free pass on anything where regulation is concerned. We are asking to be regulated as required. We want our members to be held accountable. If the Department is willing to present us requests to sign up to obligations, we are willing to meet those requests. To date, we have not been given any specific feedback from the Department on what might assist but we remain very willing to engage. We would be exceptionally happy to be held accountable and to employ whatever criteria are required under the new regulations. We absolutely sign up to the idea of audit, minimum standards for training and the most exceptionally high levels of patient safety. We are in full agreement with the thrust of the regulations. What we are not in agreement with is the fact that chiropractors have been

left outside the remit. They are not being regulated. Their use of X-rays is being prohibited and we cannot really come to terms with that.

The interpretation of the same directive in the UK recognises me as competent to be a referrer and a prescriber but in Ireland, that will not be the case. This involves the same directive and the same training and involves the same European guidelines. However, there is a very different interpretation in Ireland, one which is based on defined professions as opposed to competencies.

We have submitted a proposal to the Minister for Health, Deputy Harris, which will allow him to regulate us within the regulations. It would provide a very simple measure which would allow this to be resolved promptly. In due course, perhaps regulation under CORU and the Health and Social Care Professionals Act 2005 will provide a more comprehensive resolution for this. We have not had any feedback to date on what information to bring to the table. We have offered information on our undergraduate training and continuous professional development but to date there has been radio silence. We are not getting any feedback from the Department on our request. It has not been a "No" and it has not been a "Yes".

Deputy Kate O'Connell: Do the witnesses have any figures on the number of X-rays per head of population seen by chiropractors in Ireland versus the number seen in other countries? If chiropractors have 10,000 patients, are they all getting three X-rays in a lifetime? How does that compare internationally? Is there any indication that there is an overuse of X-ray or any sort of imaging in the Irish context? I am conscious of a recent article in *The Lancet*, which is considered a very well respected journal. The article referred to over-prescription of X-rays and magnetic resonance imaging, MRI. I am summarising a large document here. It does not just refer to chiropractors but to all referrals. The article claimed there is no improvement in outcomes in the majority of cases and an increase in interventions and surgeries. This is part of a broader discussion around overdiagnosis. Do the witnesses have any evidence that chiropractors in Ireland are X-raying people more than in other jurisdictions?

Mr. James Cosgrave: I do not have comparative data. I do not have any evidence either way on that. I can tell the Deputy-----

Deputy Kate O'Connell: No data at all - so we do not know if it is true or not. Do the witnesses have any data on it?

Mr. James Cosgrave: I do not have any data on that.

Ms Lyndsey O'Leary: We know how many exposures take place per year. The HSE did an audit on us in 2011. It found that 3,000 X-rays were taken by chiropractors in Ireland. If that is compared with some information I got this morning to the effect that 2 million X-rays are taken per year in Ireland, we find that 3,000 is 0.0015% of the total. It is not as though we are X-raying every patient who comes through the door. That was a HSE audit in 2011.

Mr. James Cosgrave: I might add that the dosage per examination from chiropractors falls somewhere between dental and medical examinations. Obviously we are not referring for or carrying out computerised tomography, CAT, scans. We are referring for plain film radiography, so the dosage is thought to be in or around 0.1 mSv.

Mr. Tony Accardi: X-rays are normally taken on the first visit of a new patient. The 130 chiropractors in the country may have up to 50,000 new patient visits a year between them. With only 3,000 being X-rayed, that is quite a small percentage.

Chairman: In the witnesses' estimation, what is the difference in attitude between Ireland and the UK in relation to X-ray facilities for chiropractors? What is the fundamental difference between the two jurisdictions?

Mr. Richard Brown: One question is what are the fundamental differences between the situation here in Ireland and the situation 60 miles up the road in Northern Ireland. The fundamental difference is that in the United Kingdom, chiropractors are permitted to take and read X-rays. They are permitted to operate X-ray units in their clinics, as well as to refer patients to other facilities for diagnostic imaging. They are entitled to do both of those things and they do so. Following on from Deputy O'Connell's questions-----

Chairman: To go back to that question, what is the underlying reason for that?

Deputy Louise O'Reilly: That was actually the crux of my question. I know there is a difference in practice. Chiropractors are entitled to make the referrals in Newry but they may not be so entitled in Dundalk, although they may have the same qualifications and practice at the same level. Mr. Cosgrave made the point that if he went to the North he would be completely covered to practise, whereas he may not be in this State. That is what I was trying to get at. There may be no difference in the person but there is a difference in what the law will and will not allow them to do.

Mr. Richard Brown: The Deputy is absolutely correct. That is the scenario. On the surface it seems rather perverse that one can jump in a car and get an X-ray at a chiropractor in the North without any problems, as one can here at present. Under the proposals, however, the situation would be dramatically different. I was particularly keen to outline the educational institutions in the UK because many of the members of the CAI are graduates of UK institutions. They have undergone exactly the same level of training as chiropractors who remained in the UK to practise, with the rights that they have to practise in terms of ionising radiation and practice generally. The proposals would create quite a significant differential in the competency and scope of practice in exercising the competency between chiropractors practising in Ireland and chiropractors in the United Kingdom, who, essentially, have undergone exactly the same training from exactly the same institutions.

Chairman: Are chiropractors in the UK or Northern Ireland regulated differently from those in the Republic?

Mr. Richard Brown: The regulation in the United Kingdom is under the Chiropractors Act 1994 which provided for establishment of the General Chiropractic Council. The General Chiropractic Council is the statutory regulator of the chiropractic profession.

Chairman: Is the fundamental difference that there is a statutory regulatory authority in the United Kingdom but there is not here?

Mr. Richard Brown: That is a difference, but the enforcement of ionising radiation regulations in the UK, although it is quoted within the Chiropractors Act and the code of practice, falls to the Health and Safety Executive in the UK. In terms of compliance, the Health and Safety Executive is the enforcing agency. My colleagues can speak more on compliance enforcement here in Ireland.

Chairman: On that point, the submission from the faculty of radiologists states, "We regard the provision for enforcement by the independent regulator HIQA as the major difference in the new legislation, which the Faculty of Radiologists wholeheartedly welcomes." Is the funda-

mental difference that there is not enforcement here but there is elsewhere, and this regulation will bring in enforcement?

Ms Olivia O'Leary Veal: At present, we are covered under two separate pieces of legislation that govern ionising radiation. SI 125 of 2000 would concern the holding and monitoring, and licensing, of the equipment. However, as a profession, we lack the protection of the statutory regulation here. That precludes us from being included in the regulations as they stand currently. In the UK, the two processes are separate. Originally, when the Chiropractors Act was brought into the UK, it was not mandated that statutory regulation was necessary for chiropractors to be able to X-ray. We believe this is a disadvantage to us as a profession as we stand because there is no statutory protection afforded to us. We are allied to the best practice of voluntary regulation which is based on the UK model of statutory regulation. The Chiropractic Association of Ireland would represent the chiropractors in the implementation of the necessary clinical governance and fitness to practise in the absence of there being a statutory model.

Deputy Bernard J. Durkan: Most practitioners in any field have complaints from time to time. Would they be aware of any complaints about the operation of X-ray equipment, the carrying out of X-rays or the referral for X-rays?

In the context of giving us an idea of what preparation they could have made or have made, have they been aware that this directive has been coming down the tracks for some time?

Mr. James Cosgrave: If I could speak first as a referrer rather than a X-ray taker, the ability to refer is fundamental. In the event of a significant issue arising on an X-ray, it is important that the pathways are in place to ensure the patient gets to see the correct person, consultant or GP without delay. Great effort is taken to ensure that there is no delay in onward referral when indicated and hence I have never experienced a complaint arising as a result of non-referral. In terms of onward referral, I would have a good relationship with the other consultants my patients might require to see in the area.

Nonetheless, with 600,000 patient visits a year, somebody will be unhappy about something. That could be the patient who has been kept waiting or did not get better or the patient felt he or she got worse. I am not aware of complaints that have arisen specifically out of a delayed referral in anything to do with X-ray. In the event of an X-ray that is deemed to be non-diagnostic, for instance, which is what I think the Deputy is asking, any time there is an issue raised to the association, the association deals with it promptly and urgently, contacts the member involved and discusses the situation to find out what has happened and what is the source of the complaint.

Chairman: On behalf of the committee, I thank the witnesses for coming in to give evidence this morning on behalf of the Chiropractic Association of Ireland.

The committee will suspend for a few moments to allow the next group of witnesses to come in.

Sitting suspended at 12.45 p.m. and resumed at 12.52 p.m.

Chairman: In this third session, we are meeting officials from the Department of Health and representatives from the faculty of radiologists at the Royal College of Surgeons in Ireland, RCSI, to discuss their views of the impact on chiropractors of the transposition of Council Directive 2013/59/EURATOM laying down basic standards for protection from the dangers arising from exposure to ionised radiation. On behalf of the committee, I welcome Dr. Tony Ho-

lohan, chief medical officer, Ms Audrey Hagerty, principal officer, environmental health unit, and Ms Siobhan McEvoy, chief environmental health officer, from the Department of Health, and Dr. Paddy Gilligan, Dr. Niall Sheehy and Dr. John Feeney from the faculty of radiologists at the RCSI.

I draw the attention of witnesses to the fact that 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 so do, they are entitled thereafter only to a qualified privilege in respect of their evidence. They 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, persons or entity by name or in such a way as to make him, her or it identifiable. I also advise them that any opening statements they have made to the committee may be published on the committee's website after this 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 or persons outside the House or an official either by name or in such a way as to make him or her identifiable.

I invite Dr. Holohan to make his opening statement. We did not receive the opening statement until this morning. Perhaps Dr. Holohan might keep that in mind for future occasions.

Dr. Tony Holohan: I accept full responsibility for that. I am joined this morning by Audrey Hagerty, principal officer, food and environmental health unit, and Siobhán McEvoy, chief environmental health officer.

I thank the Chairman and the committee for the opportunity to address them on Council Directive 2013/59/EURATOM, also known as the basic safety standards directive. There will be many acronyms and if there are any the committee needs me to clarify I am happy to do so. I am pleased to address the committee alongside the faculty of radiologists of the RCSI, which is the pre-eminent medical body to speak authoritatively on the subject of radiation, radiation exposure and its use. I hope to provide the committee with an overview of the directive and the approach being taken by the Department in its transposition with regard to the designation of referrers and practitioners. That is the medical chapter of the directive.

Overall responsibility for the directive rests with the Department of Communications, Climate Action and Environment. The Department of Health is transposing the medical provisions in the directive into Irish law by way of a statutory instrument that will repeal the existing SI 478 of the 2002 European Communities (Medical lonising Radiation Protection) Regulations 2002 and its amendments.

The directive is essential legislation the purpose of which is to protect the public, patients, workers and others from all forms of ionising radiation. lonising radiation has many beneficial applications, particularly in healthcare. However, as the use of ionising radiation increases, so does the potential for health hazards if not properly used or contained. According to the European Commission, medical procedures are the largest man-made source of radiation exposure of the population. It states that when a medical procedure is initiated and conducted appropriately all medical benefits it provides outweigh the risk associated with the radiation exposure. Without appropriate precautions, however, patients may be exposed to radiation without real clinical need or benefit, resulting in potential real harm for individual patients. There is a public health risk if there is a proliferation of radiation facilities and an unjustified increase in

the use of ionising radiation. The directive enhances and strengthens a number of concepts in radiological protection including enhanced justification requirements; it places an increased emphasis on the provision of information on the risks relating to radiation exposure and capturing and reporting on individual patient doses; provisions relating to accidental and unintended consequences are also strengthened.

In transposing the medical provisions of the directive, the Department of Health sought the advice of the HSE's medical exposure radiation unit, MERU, and a group it established to inform the transposition process. The HSE is the competent authority and regulator in respect of the existing regulations, which will change after the transposition. The Department also worked with the Health Information and Quality Authority, HIQA, which will be the competent authority in the new regulations, the Department of Communications, Climate Action and Environment and the basic safety standards directive steering group which comprises the two Departments, HIQA and the Environmental Protection Agency, EPA, which is the empowered agency under the Department of Communications, Climate Action and Environment. It engaged with several professional bodies and other groups.

The directive is quite prescriptive and there are only certain provisions where member states have discretion in its transposition. In order to garner information and views on the provisions where Ireland had discretion, the Department conducted a consultation exercise in June 2017. It posted the consultation on its website and notified likely stakeholders. It also sought the assistance of the EPA, which issues licences for the custody and use of ionising radiation equipment, to contact all licence holders to notify them of the consultation process.

The designation of referrers and practitioners for the purposes of medical exposures to ionising radiation is one area where member states have discretion, reflecting the subsidiarity in respect of organisation of health services at national level. The directive defines referrers and practitioners with certain roles and responsibilities attaching to same; member states are required to designate health professionals as appropriate. In the definition of the directive and transposed in our proposed regulations, a "referrer" is a health professional who is entitled to refer individuals for medical radiological procedures to a practitioner and a "practitioner" is a health professional who is entitled to take clinical responsibility for an individual medical exposure.

For the purposes of transposing the directive, my advice has been that we proceed on the basis that nurses, doctors, dentists and radiographers be designated as appropriate. The Department sought the advice of the MERU group on the designations and had regard to the consultation inputs. Several representations have been made to the Department, including from chiropractors, requesting that groups not previously designated be considered to be designated in the new regulations. It is imperative that the directive is transposed as soon as possible to provide clarity and certainty to the system generally and to provide the best safety protections to people who need to avail of medical radiological procedures. It is also required to enable HIQA assume its responsibilities as competent authority. The Department is working to finalise the transposing regulations in the coming weeks. I am happy to take any questions the Chairman or the committee have about this.

Chairman: I thank Dr. Holohan and invite Dr. Sheehy to make his opening statement.

Dr. Niall Sheehy: I thank the committee for inviting us to attend. The faculty of radiologists is the professional training body responsible for the training of radiologists and radiation oncologists in Ireland. Our members are medical doctors who have pursued specialist train-

ing of at least five years' duration following their medical degrees, are deemed competent via a series of examinations and assessments and are ultimately included on the specialist register of the Medical Council. We are concerned with the safe and appropriate use of radiation in medicine to accurately diagnose and treat patients. We hold positions on national and European committees that are concerned with radiation protection. We stay abreast of technological developments to ensure we are practising to current international standards to deliver the safest care to patients in Ireland. We must participate in continuing professional development, quality improvement and audit to maintain our registration with the Medical Council.

Radiologists and radiation oncologists meet the definition of "practitioner" in the new basic safety standards legislation and oversee approximately 2 million examinations per year in this country. We work alongside non-radiologist doctors, radiographers, medical physicists and nurses to ensure that radiation doses delivered to patients are as low as possible. This is known as optimisation. Patients are sent to us for radiologic investigation by medical doctors or nurse referrers for radiologic investigation. These are known as referrers. We perform the study if we believe the request to be necessary and appropriate on the basis of referral criteria. This is known as justification. In some cases, we may decide that the risk to the patient does not justify the exposure to radiation and we suggest an alternative investigation. Even at low doses, radiation carries with it a theoretical risk of inducing cancer. All the professionals we have described are registered members of organisations in this State that demonstrate commitment to training and accreditation. They participate with radiologists in hospital radiation safety committees and in research and audit. The recent development of the nurse referrer role is an appropriate model for how to incorporate a new regulated allied health professional into the radiology process. The training of nurse referrers includes the principles of radiation safety and referral. Their practice is audited by local implementation groups.

The committee is focusing its attention on whether chiropractors should be included in the legislation as referrers or practitioners. When compared with the trained and regulated healthcare professionals previously described, we have found no substantive evidence of appropriate training, referral criteria, audit or accountability in published literature from the Irish chiropractic community. We have no knowledge that the criteria and standards set out as basic in the directive by the European Commission are being met. We would not regard the self-audit of 2011 as evidence of such. While we are aware that some chiropractors are practising in a manner that is comparable to referrers and practitioners, this practice is outside the current legislation. There is no current legal basis for chiropractors to act as practitioners. This practice has only been maintained because the current legislation has no enforcement provision. Some radiology departments have performed radiology examinations on chiropractor patients. In such cases, radiologists have judged that the clinical circumstances for radiographic exposure are appropriate and have taken on the onus of becoming the patients' referrer, which is allowed for under the current law. It is important to understand that the chiropractor is not being considered to be a referrer. The radiologist is obliged to follow up the patient if significant findings are detected and further medical treatment is required.

The faculty of radiologists is of the opinion that when people operate outside the law, they make it difficult for those of us who operate within the law to compete for radiation safety resources and equipment, to motivate training of workers and to promote best practices. The faculty of radiologists regards the oversight of a regulated medical or dental practitioner as essential in ensuring patient safety. We regard any system of radiation protection as incomplete without clinical governance structures, appropriate training and audit. We fully support the Minister's position that such basic safety standards are available for Irish patients, as demanded

by EU Council Directive 2013/59/EURATOM. These standards were first incorporated after the directive in 1997 and legislated for in 2002. The new directive raises the bar on such requirements. People who did not meet the standards and operated outside the law in 2002 are not likely to meet the higher standards of the new legislation. We regard the provision for enforcement by the independent regulator, HIQA, as the major difference in the new legislation, which the faculty of radiologists wholeheartedly welcomes.

Chairman: The first three members from whom I will take questions are Deputies O'Reilly and Durkan and Senator Colm Burke.

Deputy Louise O'Reilly: I thank our witnesses for the evidence they have given. I might not be able to wait for answers after I have asked my questions because I am supposed to be somewhere else. I apologise in advance if I have to leave. I will be able to catch up on the answers that are given. My first question is a fairly basic one. We heard from representatives of the Chiropractic Association of Ireland just before the current group of witnesses came before us. They advised us in fairly plain language that they are more than willing to be bound by any regulations that are deemed necessary. They told us they would have no difficulty complying with any standards that the Department or the RCSI might want to set out. They said they would have no difficulty moving away from the current model of self-regulation. They have assured us that it is a fairly robust model. They held their hands up and fully accepted that there may be a need for further regulation. As someone who represented workers for a long time, I can assure the committee that it is rare enough for a group like this to embrace regulation. Dr. Holohan might agree that the opposite is generally the case. People do not usually embrace regulation as wholeheartedly as the chiropractors have indicated they are willing to do. Could the witnesses comment on that?

Dr. Sheehy referred to a lack of evidence of appropriate training. The chiropractors would cite the example of someone who is trained to a certain level and is practising in Dundalk. If the rules change, he or she might not be able to practise here but will be able to go 10 miles up the road to practise in Newry under the same regulations. It seems to me that this is something of a discrepancy, given that we are talking about an actual individual who could practise in both jurisdictions. The regulations are not different. The same EURATOM regulation applies. I ask the witnesses to explain their position in that context. I understand that the training received by chiropractors meets the 2014 education guidelines of the International Commission on Radiological Protection. Maybe the witnesses have an alternative view. They might advise us of that. I am aware that chiropractors use the iRefer guidelines. I am not a professional in this area. As I understand it, those guidelines are considered to be an industry standard.

I know the association has written to the Minister and is patiently awaiting a reply. I appreciate that the Minister is busy and that is fine. Dr. Holohan might be able to advise us on the status of that correspondence.

My final question relates to the national radiation safety committee. Obviously, this is all about ensuring that patients are as safe as they absolutely can be. I understand that the committee will sign off on any legislation that will have to be transposed. I am not quite sure exactly what its role is, how it is constituted or what its status is at the moment. I understand it was dissolved, perhaps not fully, before being reconstituted but I am not clear on that. Given that we are here to discuss issues of patient safety, it would helpful if we could receive some advice in that respect. I am informed that the national radiation safety committee will be considering issues relating to the impact of the transposition. If this process is not finalised, what exactly will the committee be considering? Will it be considering the final draft? What is the status of

its role in this process?

Deputy Bernard J. Durkan: I welcome our witnesses. Prior to this, did the HSE expert group that studied the need for this directive express a particular preference or antipathy, for want of a better description, towards the use of other practitioners or the access of other practitioners to X-rays and referrals? Where and from whom did the original request in relation to this directive come? Did it come from Europe? Did it come from a particular country in Europe? Did it come from this country? It seems to me from my experience with the Joint Committee on European Union Affairs that most directives usually originate back home and do the circuit before they come back. This allows us to blame Europe for introducing something for which we had devolved responsibility to Europe, or which we had approved. I do not want to put any of the members of the committee or of the HSE expert group on the spot, but I would like to know whether any of them has ever had to seek the assistance of a chiropractor. The witnesses have had complaints lodged with them, with the Health Information and Quality Authority or others regarding use of X-ray equipment and the extent of the use of X-rays by chiropractors. Have they ever had complaints made against general practitioners in the HSE for either the excessive use of X-ray services or the reading of X-rays? Have they received complaints regarding the ability of existing practitioners covered by the directive and by all the regulations? I recall at least one case not very long ago with respect to which there were very considerable reservations about the reading of X-rays. It must be fresh in all our minds. I would like a response to that question.

Have the witnesses received complaints from rival practitioners? I ask that in the broadest sense. Our competitors, even in politics, always keep us on our toes. Sometimes complaints are made by competitors as to the extent to which one does or does not do his or her job, as the case may be. What is the extent, if any, to which complaints have been made by competing practitioners?

My final point relates to HIQA. Some of us have had concerns about the extent to which HIQA, in the past, has applied rules and regulations in certain areas, which I do not propose to go into now. Dr. Holohan will be familiar with them, particularly regarding accommodation for elderly people in nursing homes, etc. I would not necessarily always agree with the conclusions HIQA reached. I am not a practitioner but neither are those in HIQA. That is the extent of my questions although I may come back in at a later stage.

Chairman: I call Senator Colm Burke.

Senator Colm Burke: I thank the witnesses for their presentations and for the work they do. Sometimes we have medical practitioners before the committee and we do not acknowledge their work and the contribution they make to our healthcare sector. It is important that we do so.

We heard from the representatives of the Chiropractic Association of Ireland earlier this morning. One of my questions related to insurance, which is a big issue that has been on my desk for quite a while. In fairness, the regulation covering medical practitioners is in place and it provides that every medical practitioner must have insurance. I introduced a Private Members' Bill in 2012, which was eventually adopted by the Department and has now gone through the whole process. The representatives of the chiropractors advised us this morning that every one of their members has professional indemnity insurance. We are talking about 130 practitioners who are providing a service to the public. They are saying they are regulated in the sense of it being within their own organisation and profession to such an extent that each member has

professional indemnity insurance. I am concerned that they are being excluded from a regulation, which makes sure that the standard they have set themselves is maintained.

If they are delivering a high level of service, and some of them are providing an X-ray service, have radiologists come across litigation involving chiropractors where professional radiologists had to give evidence in such cases? If that has not occurred, why can we not incorporate them in the regulation? We are talking about a very small number of practitioners.

Chiropractors will be prevented from making referrals. The witnesses have said that where medical practitioners refer people to radiologists for X-rays, the radiologist reviews whether the X-ray is necessary. If chiropractors refer people for X-rays, what is the concern about regulating them in the sense that they are referring people to professionals who can review and decide whether it is appropriate that an X-ray should be carried out? A radiologist would sign off on that and if the radiologist is happy that it is a reasonable request, what is the concern about including chiropractors in the regulation? That is an important question. We are talking about 130 practitioners in total and about 11 who provide radiology services. It is a very small number. With respect to the 11 practitioners who provide radiology services, we all know that radiology equipment costs a huge amount of money. It is a matter of whether we will now have 11 practitioners who will no longer be able to use very good equipment and it will simply be parked. We are not talking about hundreds of practitioners but about a very small group and about including them in the regulation.

Chairman: To complete the questions, a representative of the chiropractors stated that in 2002 the Department of Health undertook to include chiropractors under the remit of the current regulations by creating a register of chiropractors competent to take and refer X-rays but this work was not completed by the Department. Dr. Holohan might comment on what the problem was in that regard.

Is there a commitment in the Department to the setting up of a regulatory body for chiropractors? Is there an impasse, a commitment or a problem in that respect? Why is that not happening? We heard from a representative of the chiropractors that even though there are 130 in the country, they order about 4,000 X-rays a year, which is a fraction of the total number of X-rays. Therefore, it is not a huge issue. Obviously it needs to be regulated but it is not a large number of X-rays from a body which is highly motivated and highly skilled. Perhaps Dr. Holohan might answer those questions.

Dr. Tony Holohan: I thank the Chairman and the members for their questions. I will work my way through the questions one by one if that is in order. I am happy for colleagues from the faculty to interject as they see fit in terms of what I say and some of the questions that would have been referenced to them. I always have the challenge of reading my writing with respect to the questions raised.

First, regarding the lack of evidence that Deputy O'Reilly raised around appropriate training, the reality is that we have no understanding of training arrangements for chiropractors in this country. They are not part of either the formal healthcare system or, to my knowledge, the formal education system. We are reliant on the statements they have made in that we have no means, or otherwise, of validating it. The reality is that they have not been part of our healthcare system. We have no issue at all with chiropractors, either as individuals or as a collective, but it has never been the case in our healthcare system that they have formed part of what we might call our formal healthcare system. We understand that we differ in that respect from the UK. I cannot honestly advise what the policy basis was for the decision to include them in the

UK. I simply know that what was said is true in regard to its standing in the UK. That is not the case throughout most of Europe and most other European countries are in line with the situation here. Many of the points made and the questions raised here, and some of the evidence that was given earlier, to my mind relates as much to the existential nature of chiropractice as part of a formal healthcare system as much as to the specific question to which the committee is giving consideration. During the length of time I have sat on the management team of the Department of Health, which has been quite a number of years at this stage, this question has never arisen.

There was some consideration in the very early 2000s, of which some members may be aware, to the broad question of the inclusion, or otherwise, of a variety of different practitioners, who are not part of the formal healthcare system of regulation. Nothing was advanced in that regard. I cannot honestly recall what the nature of the consideration was around that question. The members might recall that it was part of a commitment, if I remember rightly and I have not read it in recent days, in Quality and Fairness, a health strategy that was published in 2001, but nothing was done to advance that case in specific terms to broaden the system of regulation. Our regulatory function in the Department has been focused on two broad areas in more recent times. One is strengthening the basis of regulation of a variety of practitioners who were already regulated. The latter include the medical profession, the nursing profession, pharmacy and others where a number of different reforms including lay majorities and others have been introduced, with more public hearings, more differentiation between fitness to practise and poor performance and a range of things of that nature. There is a second strategic intention, which is to broaden the number of practitioners who would be the subject of regulation and those who are part of a formal healthcare system. That is the work which is under way under the Health and Social Care Professionals Council, CORU. The council is working its way through 14 different groupings, each of which would be the subject of a separate system of regulation and specification. None of that architecture or apparatus exists as part of our healthcare system. While I am not saying that we would not, we do not have any plan or proposal to look at that with regard to chiropractic. That is a statement of policy as is in the Department.

I have no knowledge of the iRefer guidelines to which Deputy O'Reilly referred. That is the first I have heard of such a thing. I am not in any sense casting any aspersion on those guidelines. I have never heard of them and do not know what they are. We will be back in touch on the matter and will respond to the correspondence shortly. The Deputy asked a question about the nature of the radiation safety committee. It will stay in existence until the directive comes into force and new arrangements apply. The HSE has, *de facto*, been carrying out competent authority functions which it is not effectively empowered to carry out and there is not an appropriate separation of powers between provider and regulator. The committee may be aware of this being a finding of the inspection done by the International Atomic Energy Agency in 2015 when it made some negative findings about arrangements here, including that, that there was not separation between the provider and regulatory function. We set out the plan that we had at this point to transpose this directive. We are doing this in our system of licensing, which members may be aware will be before them for pre-legislative scrutiny in the near future. We published the heads of that before Christmas. Each of these might provide a mechanism for us to strengthen the oversight and regulation that would apply in this area. The International Atomic Energy Agency endorsed that strategic direction for how we would propose to respond to the negative findings made at that time. This work is part of us finalising some of our obligations in that regard.

On Deputy Durkan's question about where this originated, it is a process of strengthening and consolidating a set of regulations and updating those that were previously in existence.

That is my best understanding, as opposed to it being something that had a specific origin in a specific member state. It is part of a set of obligations that we now have, shared with the rest of Europe. We did not have any different role other than that we may have participated, as a number of experts from this country do, in the development of that kind of knowledge and capacity at a European level. That is what it would have emerged from. On the question of complaints, I am not aware that we have ever received a complaint about a chiropractor or, indeed, a GP regarding the conduct of an X-ray. I am open to correction on that but I do not recall ever hearing of one. The Department is not a complaint-----

Dr. Paddy Gilligan: There was one case for the board of the Radiological Protection Institute of Ireland, RPII.

Dr. Tony Holohan: I thank Dr. Gilligan. I am always happy to be corrected.

Dr. Paddy Gilligan: There was a case and prosecution in 2010 that came to the RPII.

Deputy Bernard J. Durkan: Where was it?

Dr. Paddy Gilligan: It was in Ballina District Court, based on a visit to the RPII, for non-possession of a licence.

Deputy Bernard J. Durkan: Non-possession of a licence. From whom did it come?

Dr. Paddy Gilligan: The RPII prosecuted it. That was a case of not having a licence.

Dr. Tony Holohan: I do not recall ever hearing of a complaint regarding the sort of thing that the Deputy indicated, without putting words in his mouth, such as a patient's experience of care provided by a GP. I am not suggesting that the Deputy is trying to take us to this territory. If the complaint relates to overexposure, it is difficult for patients to have any knowledge of exposure and exposure levels. They put trust in it. My radiology colleagues will be able to speak on that in a much more informed way. The challenge in healthcare is often the basis on which patients complain if they are not really able to have a means to understand the nature of the service and the quality thereof. It can sometimes, but not always, be a useful guide about quality or such.

I take the Deputy's point on HIQA that there has been, on occasion, criticism relating to standards and so on. HIQA will be empowered to be the regulatory body. It is doing a substantial amount of work. We have given substantial new resources to HIQA in the current year to enable it to build its capacity to start the work on developing standards and the competence and capacity to roll this out. Some of the people it has been able to take on from the formal healthcare system are people with substantial capacity, ability, knowledge and so on. We have no basis for this point to express, as a Department, anything other than full confidence in its capacity as an organisation to take on this function.

I take Senator Colm Burke's point about insurance. Deputy Durkan asked the question of us and for clarity, I have never attended a chiropractor. It never entered my head but, luckily, as I understand the services they offer, I have never had the need to have any recourse to avail of such services.

Deputy Bernard J. Durkan: Would Dr. Holohan have any reluctance to attend a chiropractor?

Dr. Tony Holohan: Yes. I would see no reason to attend a chiropractor. I am the chief

medical officer. The Deputy would not expect me to say anything else. I would put my full confidence in the body of general practitioners in this country, to then be referred on to the consultant body.

Deputy Bernard J. Durkan: I am not a practitioner at all but a question arises regarding, for example, to spinal problems. Would Dr. Holohan urge surgery rather than chiropractic treatment?

Dr. Tony Holohan: I would not urge surgery. I am speaking well outside my comfort zone from an expert point of view but my understanding is that many people who are referred to orthopaedic surgeons for lower back problems are amenable to effective intervention by a range of other professions, not just doctors, such as physiotherapists. A number of different innovations have been introduced into the healthcare system to help to deal with some challenges with waiting times and to have other allied health professionals play a role. They are all part of the formal healthcare system.

Deputy Bernard J. Durkan: Dr. Holohan would not see chiropractic as a helpful addition to the menu of assistance available to people who suffer from back or spinal problems.

Chairman: Sorry, Deputy Durkan. I do not really think we can put the chief medical officer under pressure to give his personal opinions.

Deputy Bernard J. Durkan: He has gone that route himself.

Dr. Tony Holohan: I would not put it in those terms. Chiropractors are not part of the formal healthcare system. We do not plan and organise our services on the basis of anything other than the professionals who are part of our healthcare system.

Deputy Bernard J. Durkan: If they were part of the formal health system-----

Dr. Tony Holohan: That is a matter of conjecture and I do not know what role they would play. Speaking personally and honestly, I have very little knowledge or understanding of them. I went through medical school, medical training and all that. Never, in the time I spent in that, did I receive any tuition, knowledge or guidance on the nature of chiropractic, what it is or what it does. I am not saying that is either a good thing or a bad thing. It is simply a statement of fact to support the fact that I have very little understanding of what chiropractic is.

Deputy Bernard J. Durkan: That is interesting.

Dr. Tony Holohan: They are not part of the formal healthcare system. We have good and detailed policy understanding, since I mentioned physiotherapy in this context, of the role the physiotherapist can play. That is why I can talk in the terms that I am about development of services. To answer the Deputy honestly, I have thankfully never had such recourse.

Senator Colm Burke asked, if there has not been any evidence that radiologists have been called to give evidence of harm, whether that would be a sufficient basis for us. That would not be a sufficient basis for us to take a step or sufficient grounds for us to incorporate this. We are not in the business of excluding anybody. The purpose of this directive is to identify and empower appropriate professionals as either referrers or practitioners, which is what we are doing, and then to empower various competent authorities with the means to be able to ensure that, from the point of view of the protection of the public, the people who are empowered to operate the legislation are the ones operating the legislation and that nobody else is operating it

as if they were empowered. That is the intention. It is not about any individual grouping or the naming and exclusion of any individual grouping. It is the empowering of named and identified professionals. There is also an important point for me to address relating to the Senator's question on referral. We have an ordinary use of referral, in the way we talk, in that people do get referred. One person can be referred to another person. Referral under the Act carries with it privileges that are set out in the legislation. Referral in the meaning of the directive is not the same in the sense of if, for example, a chiropractor referred a patient to a GP for an opinion. That could be regarded as a referral in terms of its common meaning but it is not a referral under the legislation. It is important not to conflate those interpretations. I do not suggest the Deputy is doing so but it has been done in some public discussion on the issue.

A commitment of which I have seen documentary evidence was made in 2002. I do not understand the reasons for it not moving forward and am not aware of the discussions in that regard. Now, a substantial number of years later, any such question must be considered in the context of the directive and a strengthened set of arrangements from Europe that seek in broad terms to tighten up the arrangements that already exist in respect of the use of radiation for the purposes of protecting patients and the wider public from exposure.

As to the wider question asked by the Chair, there has been no commitment to set up a body for the purpose of regulating chiropractors or others. That has never been expressly considered. That is not to say that it would not be given positive consideration but, rather, it has never been considered.

Chairman: Dr. Holohan referred to chiropractors as not being part of the formal healthcare system.

Dr. Tony Holohan: Yes.

Chairman: Would they be required to become part of that system in order for them to be regulated?

Dr. Tony Holohan: Yes. Regulation would effect a set of arrangements whereby the nature of the content, obligations, accountability and oversight of any given profession would be set out with substantial clarity. It is not just a list of designated individuals but, rather, contains a significant amount of detail. Substantial detail in terms of scope of practice has been set out in some of the more recent work in regard to regulated professions as part of CORU. The relationship of that scope of practice to the practice of other practitioners would be worked out and negotiated in great detail before ultimately being set out in legislation or legal frameworks under legislation. It would have to have regard to the level and standards of education and training and so on, but we currently have no arrangements in this country in that regard and we, as an organisation, have little formal understanding or knowledge of them at this point. All of those kinds of details would be specified for any profession that had to be brought to and through a system of regulation, just as they are for the medical and nursing professions and those which have been regulated for a long period.

Senator Colm Burke: What is the problem with chiropractors having the power to refer on for radiology or extra services? The radiologists are the experts who will decide whether or not it is appropriate that there be an X-ray. What is the concern in terms of chiropractors having that power and that being removed from them under the proposed regulation?

Dr. Tony Holohan: The arrangement described by the Senator is a situation whereby an

individual is referred by a chiropractor, possibly by way of letter, to a GP or other medical practitioner.

Senator Colm Burke: No, referred specifically for an X-ray to a radiologist, who is the expert and can decide whether or not it is appropriate. Under the proposed system, the chiropractor would have to send the person back to the GP, who would then have to refer on to the radiologist. What is the problem with a person who has an expertise in a particular area deciding it appropriate that before he or she carries out any further treatment the patient should be reviewed by way of X-ray, and referring the patient to a professional radiologist who can decide whether an X-ray is appropriate?

Dr. Tony Holohan: Referrals to specialists in our hospital system operate through our general practitioners. That is how our system is organised.

Senator Colm Burke: I acknowledge that. However, some radiologists work in a private capacity.

Dr. Tony Holohan: That is a different matter.

Senator Colm Burke: Yes, but the proposal will remove that power from them. A chiropractor will have to apologise and send the patient back to his or her GP, who will then refer the patient for an X-ray.

Dr. Tony Holohan: My colleagues may have a view on this issue. A situation involving a radiologist working in the private system who receives correspondence such as a referral by a chiropractor will not be covered by this legislation. It would be entirely open to the radiologist to decide if he or she wants to conduct that X-ray. If that is done, he or she is doing so as a practitioner under this regulation and there is no problem in that regard in terms of the regulation. The ultimate accountability in such situation would clearly lie with the radiologist making the determination.

Dr. Paddy Gilligan: I wish to back up the comments of Dr. Holohan in terms of us not anticipating a change in that regard. That the radiologist will become the referrer in the absence of a prescriber is not explicitly dealt with in the new legislation but the provision should be maintained.

As regards complaints and incidents, I am a member of the national radiation safety committee. Since 2009, we have had a radiation incident reporting system to which facilities reported multiple exposures, over-exposures or any incidents relating to diagnostic radiology or radiotherapy. Approximately 40 to 50 incidents are reported per year and there is a smaller number of incidents. We have not had any reports from chiropractors to date but that may or may not reflect good or bad practice.

Senator Colm Burke: Moving away from the area of radiology, I wish to raise the practice of people now providing scanning services, which is totally unregulated. I recently heard of a person who had a scan on a Saturday and was advised that the baby she was carrying had died but there was no mechanism in place to refer her on to a medical practitioner. A mother was left in limbo over a weekend to deal with that new information provided by someone offering private scanning. There is no regulation of that area.

Dr. Tony Holohan: It is likely that was ultrasound scanning, given the nature of the procedures done to determine pregnancy and so on. The fact that it was on a pregnant woman makes

it highly unlikely to have involved ionising radiation.

Senator Colm Burke: I accept that but I compare that situation with that of chiropractors who provide a service and are prepared to refer on to specialists who provide a very comprehensive service. We seem to be excluding people who are providing a service and regulation and who have insurance and I am concerned by that.

Dr. Tony Holohan: I understand what the Senator is saying. Several of those points have been made to us but we have no knowledge of that other than those declarations and statements. The reality is that the proposed and previous regulations do not make provision for people other than those I have mentioned and who we propose. We are still working on this as an organisation and, as I said, we hope to finalise our thinking on the matter over the coming weeks and bring it to a level of finality. However, Senator Burke's use of the word "referral" is not in accordance with the intended meaning of the word as set out in the legislation. A definition of "refer" and so on is set out in the directive.

Deputy Bernard J. Durkan: I have an innocuous question. In the run-up to this requirement, what discussions took place between the HSE expert group and chiropractors? Obviously, if major changes are going to take place, the normal routine would be to have discussions with the bodies most likely to be affected. Has the Health Information and Quality Authority, HIQA, in its present capacity, had discussions with chiropractors as to the advisability of regulations or the extent thereof? Has the Department had discussions with chiropractors regarding the extent of the proposals, how it might affect them and how they might be required to act before being admitted into the formal health regime in this county?

Dr. Tony Holohan: My colleagues may be able to assist me in answering in terms of setting out some of the detail of the consultation. We ran a consultation process last summer and invited people to come forward. We heard from a number of bodies. We took additional steps to select the representative body and the chiropractors who were holders of licences. My understanding is that we did not hear anything from them as part of that consultation.

Deputy Bernard J. Durkan: Who was consulted?

Dr. Tony Holohan: A range of different bodies was consulted. Obviously, the HSE will be a substantial source of expertise from our point of view. The expertise in this country, such as it is, resides in two main sources. At the practitioner level, it resides within the public services. From a professional point of view, it resides with the professional training bodies. The Faculty of Radiology is the pre-eminent such body in terms of medical practice and use of radiation. We would have had engagements-----

Deputy Bernard J. Durkan: And consultations.

Dr. Tony Holohan: -----with those kinds of bodies as well as with HIQA. In the ordinary course of engagement on legislation, we always engage with those bodies that are, in effect, going to be at the front and at the centre in the effective operation of legislation and regulation. That is exactly what we did in this case. We are still continuing with that process. It is not at an end.

Deputy Bernard J. Durkan: Did consultation take place with the professionals in chiropractics who say they have a recognised qualification at master's level? Obviously, some have less and some have more. Did the Department engage in such consultation? Did the expert group engage in consultation in an effort to identify how best it might proceed in bringing this

within the national health regime?

Dr. Tony Holohan: The regime I was referring to is more relevant to the wider context, which is the existential nature of chiropractics as a service and as part of the public health system. That is not the question that is before us now or that we were consulting on. As far as I am aware, we have received no representations, in a broad sense, in respect of that.

Deputy Bernard J. Durkan: It is an important question. I would have thought that in order to come to a conclusion on how to proceed in a particular situation, there is automatically a requirement to consult the profession that is about to be affected by the proposal.

Dr. Tony Holohan: We would have taken the view that chiropractors had an opportunity to engage in our consultation process, but did not do so. They came to us by way of correspondence. We had engagement with them. A meeting took place with them. As I have said, we have not completed our consideration. The other point is that chiropractors who provide services in the way described by the Deputy are doing so outside the terms of the regulations as they currently exist.

Deputy Bernard J. Durkan: We are aware of that, but we are talking about compliance with a new regulation. I suggest that the extent to which the professionals in this area, as they see themselves,-----

Dr. Tony Holohan: Yes.

Deputy Bernard J. Durkan: -----need to be consulted is an obvious question-----

Dr. Tony Holohan: We are not-----

Deputy Bernard J. Durkan: -----that we need-----

Dr. Tony Holohan: We sought to consult them.

Deputy Bernard J. Durkan: The Department sought to consult them.

Dr. Tony Holohan: We did so because we agree with what the Deputy is saying.

Deputy Bernard J. Durkan: They did not respond.

Dr. Tony Holohan: No.

Deputy Bernard J. Durkan: They might have something to say about that. However, I will let Dr. Holohan continue.

Dr. Tony Holohan: That did not stop us from engaging with them when they sought further engagement. We have no difficulty in talking to anybody.

Deputy Bernard J. Durkan: Has provision been made for any intention on the part of the Department to conclude that discussion or dialogue before the directive comes into operation?

Dr. Tony Holohan: The directive will not come into operation until the Minister signs the regulations.

Deputy Bernard J. Durkan: We know that.

Dr. Tony Holohan: We have to bring a number of pieces to some finality-----

Deputy Bernard J. Durkan: That is not my question.

Dr. Tony Holohan: I understand. I mention that in answering the question. As well as giving further policy consideration to this matter, we are still in dialogue with a number of organisations. We have not completed our full consultation.

Deputy Bernard J. Durkan: The process is not completed yet.

Dr. Tony Holohan: The process is not completed until it is completed. Ultimately, we will present the Minister with the final proposed set of regulations. As part of that, we will receive legal advice. We expect to get legal advice on the broad totality of this very shortly. That will be part and parcel of the final analysis of what will go into the regulations.

Deputy Bernard J. Durkan: Will the consultation process be completed to the Department's satisfaction before this is presented to the Minister for enactment?

Dr. Tony Holohan: We will not present something to the Minister for him to sign unless we believe we have heard and understood the perspectives and points of view of all the relevant organisations we need to hear from.

Chairman: I thank Dr. Holohan.

Dr. Niall Sheehy: I would like to clarify some points that have arisen. A comment was made about iRefer. For the information of the committee, iRefer is a set of guidelines issued by the Royal College of Radiologists in the UK with regard to efficient and safe referral for radiology. We endorse iRefer, which is an international gold standard.

A number of comments made by members, including what Senator Burke said about insurance, come back to the issue of statutory regulation. As radiologists and other doctors are legally registered with the Medical Council, they need to have insurance. Doctors who are not part of the Medical Council can be prosecuted. Issues with poor performance by radiologists, which have arisen in the past, are remediable to the Medical Council. Doctors can and do have their licences to practise removed or restrained by Medical Council practitioners. We are not a self-regulating body.

The question of the referrers' clause has been clarified by the chief medical officer. As we said in our submission, there is a huge amount of confusion about the terminology used when someone is doing a referral, doing a prescription or doing a test. Essentially, in radiology terms, in most cases it is a radiographer who takes an X-ray of one's spine. A radiographer is not legally permitted to do this unless he or she has received a referral from someone who is allowed to refer under the legislation. At present, this can be a medical doctor or a nurse referrer. If a chiropractor sends in a request to a radiology department, the radiologist or the practitioner in charge can look at that request and say that it is justified. In such circumstances, that radiologist is legally deemed to be giving the referral to the radiographer that permits him or her to perform the examination. Our understanding is that this will continue under the new legislation. This practice should not change, as we understand it, but perhaps that can be clarified further.

The final question that was asked related to competing practitioners. This is not the issue for us. As we heard in previous testimony, most of the radiology examinations referred by chiropractors are being done in the radiology system. A small volume of studies is being done outside of that. I do not think my colleagues have anything else they would like to say.

Chairman: On behalf of the committee, I thank the faculty of radiologists from the NCSI and Dr. Holohan and his colleagues from the Department of Health for coming in to give evidence today.

The joint committee adjourned at 1.50 p.m. until 9 a.m. on Wednesday, 2 May 2018.