DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE AGUS LEANAÍ

JOINT COMMITTEE ON HEALTH AND CHILDREN

Déardaoin, 12 Márta 2015

Thursday, 12 March 2015

The Joint Committee met at 9.30 a.m.

MEMBERS PRESENT:

Deputy Catherine Byrne,	Senator Colm Burke,
Deputy Robert Dowds,	Senator John Crown,
Deputy Peter Fitzpatrick,	Senator Jillian van Turnhout.
Deputy Seamus Healy,	
Deputy Billy Kelleher,	
Deputy Eamonn Maloney,	
Deputy Dan Neville,	
Deputy Caoimhghín Ó Caoláin,	

In attendance: Deputy Michael McNamara.

DEPUTY JERRY BUTTIMER IN THE CHAIR.

The joint committee met in private session until 10.04 a.m.

Cost of Prescription Drugs: Discussion (Resumed)

Chairman: Today's first session is a follow-up briefing from the HSE and Department of Health on the cost of pharmaceuticals. The second session will start at about 11.30; we have moved the time back a bit. In that session we will hear from Dr. John Holmes on the general scheme of the public health (alcohol) Bill.

I apologise to our witnesses for the delay in beginning. We held our first meeting last Thursday on the cost of prescription drugs and pharmaceuticals in Ireland. The stakeholders at that session included representatives from the IPU and the pharmaceutical industry. We also heard from Professor Colum Dunne from UL. A number of issues were raised concerning negotiations between the pharmaceutical industry, the HSE and the Government, which we want to revisit this morning. I thank Mr. John Hennessy, Mr. Shaun Flanagan, Mr. Paddy Burke, Professor Michael Barry, Mr. Fergal Goodman and Ms Teresa Cody for attending today. I also thank Mr. Ray Mitchell for his co-operation and assistance in organising this meeting.

In private session the committee discussed the fact that Alexion has twice declined our invitation to appear before the committee. The committee has agreed to publish the correspondence with Alexion. On your behalf I express disappointment and regret that its representatives did not appear.

I remind people to turn off their mobile phones, as they interfere with the broadcasting of the proceedings.

I remind people of the position on privilege. Witnesses are protected by absolute privilege in respect of the evidence they are to give this committee. If they are directed by the committee to cease giving evidence in relation to 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 persons or entity by name or in such a way as to make him, her or it identifiable. Members are reminded of a long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the House or any official by name in such a way as to make him or her identifiable.

I ask members to keep to the time limit, which I believe is seven minutes, as we have two busy meetings.

Mr. Fergal Goodman: I am very pleased to attend today's meeting to discuss the cost of pharmaceutical drugs. I am assistant secretary in the primary care division in the Department of Health. I am accompanied by my colleague Ms Teresa Cody, principal officer, primary care unit, and her colleague Emma Jane Morgan, who is assistant principal in the unit, is behind us.

Among the significant factors that come into play when we discuss the cost of pharmaceutical drugs is the demographic trend, which has a significant effect on consumption of the drugs and the cost drivers. Population growth in Ireland in the earlier part of this century outstripped that of Europe as a whole. Ireland's population is still increasing, although now at rates similar to the EU average. There was 21% growth in the 65-and-over population between 2006 and

2013, and growth in the older age groups will continue at this order of magnitude in the years to come. In particular, the cohort of people aged over 80 is increasing by about 4% a year and, of course, they are high users of all health services. By 2021, the population over the age of 65 will have increased by close to 40% since 2011, representing an additional 200,000 people.

Life expectancy has increased substantially in recent years. Between 2002 and 2012, male life expectancy at birth increased by 3.7 years, and is now at 78.7. For women it increased by almost three years in the preceding decade and is now above 83. Much of this is obviously attributable to advances in medical science and in the treatments available, including drug treatments. As well as bringing very clear benefits to individuals and to society generally, increased life expectancy means that as people live longer, they are likely to do so with an increasing burden of chronic disease and increasing dependency on health services. Despite the success of policies aimed at controlling drug costs, we need to continue the efforts to maximise the benefit to individuals and society of the medicines used in Ireland in a way that is affordable.

This is the backdrop against which the cost of drugs and medicines has been under intense scrutiny in recent years. This has not only been highlighted at Government level, but it was also a significant issue for the troika during the bailout period. The Department and the HSE have played a significant part in delivering this reform. This has achieved benefits for the Exchequer and has assisted in managing the pressures on the very constrained health budget in recent years. It has also brought benefits to patients in terms of facilitating the adoption of innovative new drugs and in substantially reducing the prices that people pay across the counter in the pharmacies.

I will outline some of the key policy developments that have resulted in reductions in the price of thousands of medicines. Price reductions of the order of 30% per item reimbursed have been achieved between 2009 and 2013. The average cost per item reimbursed is now running at 2001 to 2002 levels.

As the committee will be aware, we have had a series of agreements with the Irish Pharmaceutical Healthcare Association, IPHA, and the Association of Pharmaceutical Manufacturers in Ireland, APMI, representatives of which the committee met last week. The agreements in 2006 generated savings in the region of €250 million, and a further €250 million in savings flowed from the subsequent agreements in 2010 and 2011. The current agreement was negotiated in 2012, and that had a value in excess of €400 million in the period up to 2015. It expires, as members will be aware, at the end of October this year. In broad terms, about half the financial value of the deal relates to reductions in the cost of patent and off-patent drugs, while the other half, or €210 million, is related to the State securing the provision of new and innovative drugs. Also in 2012, a new agreement was reached with the APMI which significantly reduced the maximum price paid for generic products. That price was further reduced by agreement in 2014, with the result that the price differential between off-patent drugs and most generic equivalents increased from 5% to approximately 20%. Taking these agreements together, we estimate that cumulative savings in excess of €1.5 billion have been achieved in the nine years since 2006.

On generic substitution and reference pricing, members will be aware of the Health (Pricing and Supply of Medical Goods) Act 2013. This important legislation provided for the introduction, on a statutory basis, of generic substitution and reference pricing and brought about significant structural change to the system of pricing and reimbursement of medicines. The introduction of generic substitution and reference pricing promotes price competition among suppliers and ensures that lower prices are paid for these medicines. Generic substitution al-

lows pharmacists to substitute a cheaper generic equivalent, at the patient's request, when a more expensive product has been prescribed. Generic medicines are as safe and efficacious as proprietary products and are subject to the same requirements of quality, safety and efficacy. The Health Products Regulatory Authority, HPRA, has responsibility for the designation of interchangeable medicines under the Act.

Under the 2013 Act the HSE is responsible for reference pricing, which involves setting a common reimbursement amount for designated interchangeable groups of medicines. Only the reference price is reimbursed by the State, thus incentivising the patient to opt for a generic medicine at or below the reference price. Reference pricing coupled with generic substitution therefore provides patients with an incentive to opt for the cheapest available product but does not impose unavoidable additional costs on patients. Generic substitution has been introduced incrementally, with the HPRA prioritising those medicines which will achieve the greatest savings for patients and the State. This process will continue until all relevant items on the reimbursable lists have been assessed. Reference pricing has also been successfully introduced, with the price of many products being substantially reduced from previous levels.

The impact of this legislation has been positive in terms of increasing the level of generic penetration in the Irish market. As part of the troika commitments, a target for generic penetration of the off-patent market by volume was set at 70% by 2016. The target to be achieved by the end of 2015 was 65% and 70% by the end of 2016. However, by quarter four of 2014, generics already accounted for approximately 68% of the total off-patent market, so the target set for the end of 2015 has been already exceeded.

The recent European Commission staff working document on Ireland acknowledged the substantial cost savings that have been made by the introduction of generic substitution and reference pricing. Reference pricing was expected to deliver savings in the region of €50 million in 2014, which is retrospective at this stage, and a further €25 million in the current year. The Act of 2013 also improved and updated the statutory basis for the supply of medicines and other prescribed items under the general medical services, GMS, and community drugs schemes.

Other important initiatives, on which members can hear more from colleagues - including Professor Michael Barry, who is here with us - include the establishment of the medicine management programme, which has a focus on cost-effective prescribing and a reduction in drug expenditure through more rational prescribing.

The measures I have briefly outlined - I will keep this brief, as it is a technical area - have been instrumental to achieving the significant savings required in this sector in recent years. That said, the State still continues to face upward pressure on the drugs bill. This is due to a range of factors, including the demographic trends to which I referred, the significant increase in recent years in number eligible for the GMS and community drugs schemes, and the desire on the part of clinicians, patients and the public generally to have access to the newest and most innovative medicines, with the associated high costs.

In order to ensure that funding is available to enable patients to have access to new and innovative drugs, it is necessary to continue to pursue savings and efficiencies in expenditure in this area. The Minister's and the HSE's preference is for these additional savings to be delivered in co-operation with the pharmaceutical industry, so long as it enables the needs of all parties to be met. However, I note that section 21 of the Health (Pricing and Supply of Medical Goods) Act 2013 affords the HSE powers to review and alter prices. This is an option that is open to HSE to exercise in the event that agreed approaches are not capable of meeting the funding pressures

that the HSE faces in regard to drugs.

The Department and the HSE, with a strong level of commitment, most of which precedes my time in my current role, have successfully implemented a range of policy measures, which I have outlined. Colleagues from the HSE will be able to provide further detail, but it is clear that significant cost savings have already been delivered for the Exchequer, resulted particularly in reduced prices being paid by the public. Given the substantial cost pressures that the health service will continue to face in the coming years, this is an agenda we will continue to pursue in many ways in order to further reduce the cost and ensure the affordability of medicines for the State and for patients.

Chairman: Thank you, Mr. Goodman. I call Mr. John Hennessy, national director of the primary care division in the HSE.

Mr. John Hennessy: In the interests of time and with the Chairman's permission, I will skip through some of the text in my opening statement, as it is on the lengthy side, but I will cover the key points. I thank the Chairman and members of the committee for the invitation to attend today to discuss the cost of pharmaceuticals.

We welcome the opportunity to outline the progress that has been made with regard to the price of medicines in Ireland during recent years. I am joined by my colleagues Mr. Shaun Flanagan, chief pharmacist, Mr. Patrick Burke, assistant national director, and Professor Michael Barry, chief pharmacologist at St. James's Hospital and head of the HSE medicines management programme.

The HSE provides reimbursement support for medicines and appliances across three main community drugs schemes – the general medical services scheme, or the medical card scheme, the long-term illness scheme, and the drugs payment scheme. Additionally, arrangements are in place for the supply of hospital-initiated high-tech medicines through the community pharmacy contractor network of approximately 1,800 pharmacies covering the country and a population of approximately 4.6 million people. It should be noted that the HSE does not set the prices that pharmacists charge to patients on private prescriptions, but only becomes involved when a claim is made under one or other of the aforementioned community drug schemes. For example, it does not cover patients who pay less than €144 per month and are not covered under either the GMS scheme or the long-term illness scheme.

In terms of current expenditure, the HSE reimbursed the following amounts in 2014 on medicines and appliances across those three main schemes and in the high-tech medicines area. The expenditure covered the ex-factory price of €1.3 billion, wholesale mark-up costs of €107 million, pharmacy fees of €379 million and VAT of €115 million, giving an overall total expenditure of €1.92 billion. Those figures cover reimbursement claims for medicines and appliances dispensed in 2014, involving approximately 70 million separate prescription items. Aggregate spending on the GMS scheme, the drugs payment scheme and long-term illness scheme has decreased since 2009 despite the growth in numbers, changes in eligibility during that period and the introduction of more expensive new medicines such as new oral anticoagulants. This is due to a sustained and ongoing programme of price reductions, on which I hope to elaborate during the course of my presentation. The exception in that respect is expenditure on high-tech medicines, which has increased from €315 million in 2009 to €485 million in 2014. This is as a consequence of the introduction of some highly expensive new drugs and medicines and increased use of some existing products.

With regard to price reductions, expenditure on reimbursed medicines has remained stable between 2009 and 2014 despite the introduction of that range of new medicines. The average price of an item dispensed on the GMS scheme has decreased to below the price paid in 2002, and the average long-term illness scheme price is less than the price paid in 2000. Detailed information on that is outlined in appendix 3 to the information pack that has been made available to members. Details of the list of actions taken to achieve those reductions are also available. The price reductions have resulted in savings and cost avoidance for the State, amounting to €1.5 billion over the period in question. A significant proportion of the money saved has been invested in new medicines for Irish patients.

The focus on savings has been concentrated in three key areas, the first of which is new patented medicines. The maximum price a company can seek when it applies for reimbursement for a new patented medicine is the average of the approved prices across nine EU member states, as detailed in the 2012 Irish Pharmaceutical Healthcare Association agreement. Those member states are listed in the document. The 2012 agreement also required companies to submit an evidence dossier containing clinical and economic data in support of reimbursement at the price applied for. This was subsequently underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013, which my colleague Mr. Goodman mentioned. The 2013 Act requires the HSE to consider detailed criteria, as outlined in appendix 5 of the information document, when making decisions. The net effect is that companies must provide robust evidence to justify the price of every new patented medicine. Company dossiers are evaluated by technical staff at the National Centre for Pharmacoeconomics, which is based on the campus of St. James's Hospital and headed by Professor Barry, who is in attendance this morning. Summaries of all the evaluations carried out are publicly available on the website.

Under the 2012 agreement, a medicine that satisfies a cost-effectiveness threshold of €45,000 per quality-adjusted life year progresses to reimbursement. In exceptional cases, medicines are considered for reimbursement above the threshold, subject to meaningful negotiations having been concluded. The HSE has been increasingly faced with what individual companies consider are exceptional medicines and increasing expectations that the State will be in a position to reimburse medicines which in no way approach any conventional understanding of cost-effectiveness. In such cases, the HSE, like pretty much every other health care system worldwide, is faced with a difficult decision on whether to fund a medicine which the company dossier has demonstrated is not an economic use of resources. The HSE would like to be in a position to reimburse all medicines, but that is not possible given the competing demands for resources. Members will remember that the director general of the HSE, Mr. Tony O'Brien, recently appealed to Alexion Pharmaceuticals to reconsider the price it charges for eculizumab, or Soliris. The HSE's national drugs committee considers all the evidence provided and issues its advice on the basis of pricing offers made by companies and in light of the degree of unmet need, clinical evidence, cost-effectiveness, budget impact and any other relevant factors regarding whether the medicine should be reimbursed.

The second area of focus for control is the off-patent medicines sector, which has also been the subject of a series of downward price revisions under national agreements. When they are launched, generic medicines are now required to be 60% lower in price than the pre-patent expiry price of the branded product. The first reference prices were set on 1 November 2013. As of January of this year, the HSE has set reference prices for 110 interchangeable groups across 37 medicine combinations. It is now reimbursing approximately 1.5 million items per month in relation to reference-priced medicines. The aim in setting reference prices is to achieve the lowest possible price commensurate with continuity of supply. The industry has consistently

claimed the HSE is setting its prices too low. On the other hand, some commentators would contend that our prices are still too high. We believe the decisions taken to date are proportionate and reasonable, and are consistent with continuity of supply and the policy of reducing Irish prices to acceptable levels. This project is ongoing.

The third main area of control is the HSE medicines management programme, which is headed by Professor Barry and was established in January 2013 with the aim of enhancing safe, effective and cost-effective prescribing of medicines in the Irish health care setting. The details of the programme's wide range of ongoing activities are outlined in appendix 9 of the information pack. One of the main ways the programme communicates with prescribers is through a series of meetings with general practitioners. These meetings are held across the country in collaboration with the Irish College of General Practitioners, which invites the programme to make presentations on prescribing issues. This has proven to be an extremely valuable way of getting key messages across to prescribers. The programme has met more than 1,100 general practitioners over the past 18 months.

I would like to comment on the impact of these measures. The HSE and the State have benefited from price reductions on new medicines and are regularly paying lower prices than companies would have applied for or indeed would wish. Our most recent audit revealed that Irish prices are now at the average of the nine-country basket and are close to the average price of a wider group of EU member states. However, Irish prices are still above the average calculated across the full 28 EU member states when the more recent entrants from Eastern Europe are included. In the off-patent category, I should point out that when the 2013 Act was introduced, the HSE was reimbursing in excess of €22 million per month on medicines reference-priced in 2014, but by December 2014 this amount had been reduced to €10.3 million per month. Savings of €47.4 million were achieved in 2014 from reference pricing alone. The full-year impact of that will amount to €60 million. This is of course ongoing. The cost of reference-priced drugs now is between 70% and 80% lower than the price paid when medicines were on patent. As of the final quarter of last year, generics now account for 68% of reimbursed claims.

The HSE is continuing with reference pricing. We expect to deliver in excess of €25 million in additional reference-priced savings in 2015. The HSE has been successful in providing access to many new medicines while reducing the prices of new and existing products. The figures speak for themselves. Savings of €1.5 billion have been achieved to date in this complex area. Members will understand that the various stakeholders involved will try to protect and defend what they have and resist changes that may reduce their incomes. We remain committed to ensuring pricing in Ireland is reasonable and fair. We want to provide access to as many new medicines as possible from within the resources available to us. At all times, our concern is to ensure continuity of supply and avoid causing additional co-payments for patients when making pricing decisions. My colleagues and I will endeavour to answer any questions that members may have.

Chairman: I thank Mr. Hennessy and his colleagues for the very informative pack that members have received. I call Deputy Kelleher.

Deputy Billy Kelleher: I welcome everybody. We acknowledge and welcome the improvements that have been made in terms of value for the taxpayer when medicines are being purchased on behalf of the State. It is obvious that demographic factors will present huge challenges from now on. The witnesses mentioned the increase in life expectancy and the improvement in the treatment of chronic diseases. We are probably slow to address some of the issues that will lead to an increase in the prevalence of chronic diseases in the years ahead.

Obesity and smoking will lead to an increase in diabetes, heart conditions and smoking-related illnesses. We are making efforts, but maybe we are not gaining as much ground as we would like. High-tech medicines that are tailor-made for small cohorts of people are also becoming more prevalent. There will be huge pressures in the years ahead.

I would like to take a slightly historical view of these issues for a moment to help me to get my head around them. I applaud the HSE and everyone else responsible for the progress that has been made. The 2006 reductions agreement generated savings of approximately €250 million. A further €250 million in savings was generated by agreements reached in 2010 and 2011. That leads me to believe there was a great deal of fat in the system. Perhaps the question I will ask in that context will be asked by another Oireachtas committee at some stage. Was there that much fat in the system because of a lack of political will, or because appropriate mechanisms were not in place? Was the State being jockeyed by the Irish Pharmaceutical Healthcare Association and the Association of Pharmaceutical Manufacturers of Ireland on a constant basis in terms of the cost of available medicines? What allowed the HSE to reduce the price of medicines to the State by such an enormous amount in such a short period? Was it lack of regulation or lack of legislation? Was it the comparators with the nine European countries in the basket? Was it lack of political will or was it just the inability of the State to negotiate? One would have to say that the savings made suggest that there was a poor negotiating stance in the first place. I am not making a statement of fact but just inquiring on that issue.

The other area that is of concern to me, if I have understood correctly, is that if a company applies for reimbursement of its on patent new drug, the nine European countries are used as a basket. If the drug is not available in those nine European countries, is it correct that it is to a minimum of three countries? Is there huge potential for companies to manipulate the price? Let us be very clear, if there are nine countries, there is a better chance that there will be an average, but if a company is going to make its drug available and knows that the price is going to be based on three countries, it will obviously make it available to the dear ones first and work out from that. Is there not a huge flaw in the system there in terms of pricing? The average will always come from the highest down as opposed to from the other way up or from the middle. I would like further clarity on that. If that is the case, who decides, first and foremost, the basket of countries and who decides which three countries the medicine will be made available in first? It is obvious it will be the companies. There is quite a weak area in the mechanism of adjudication of the price. Is that a regulatory matter for the European Union or is it a State matter? Where do we go in terms of trying to address that weakness in pricing?

As an aside to Mr. Flanagan on Soliris for the treatment of PNH, I am led to believe that the Government, the Department or the HSE has made an announcement that Soliris will be made available to individuals with PNH but I am also led to believe it is not available yet. Soliris has been referenced quite a number of times and reference has been made in Parliament that this issue has been resolved, but I am led to believe that it may not be resolved for the people who are waiting for it so I would like clarity on that issue.

I have raised this issue without saying that it is factual but there has always been a strong belief among some people that there have been sweetheart deals in this State for many years, with some drug companies in previous times being induced to invest further or locate here in the first place, perhaps by the IDA and others or through back channels, and it is obvious the reason they come here is our corporation tax rate. We have a politically stable environment, we have a reasonably bright graduate workforce and we now have a critical mass, so I accept that there are many other factors why they are here. However, there was always a view in the earlier part

of industrial development policy that there were inducements other than the obvious attractions the State provides upfront. Has Mr. Flanagan ever come across that particular issue or those suspicions in terms of dealing with various pharmaceutical companies and the pricing of same?

In terms of cross-Border and the continual fluctuations in sterling versus the euro and, in particular, how it is fluctuating now, is there any way of addressing the issue of people in the North coming South or *vice versa* when it suits or when it is more profitable?

I want a small bit of information on parallel wholesaling where if a drug is cheap in Ireland, it is purchased in Ireland through the wholesale system and sold into the dear countries. Is this done by pharmacists? We all know about the free movement of goods and services but if a product is sold to the State, one would think that it should stay in the State and not be shipped out in containers to some other country. Is there a weakness there as well in the context of parallel wholesaling through the European Union countries?

Deputy Caoimhghín Ó Caoláin: I thank the Chair and welcome the witnesses. The first thing to say to Mr. Goodman is there is credit due for the effort made and the fact that there have been significant reductions achieved in recent years. I want to acknowledge that at the outset. I put the question because there is a common view that the Department or our negotiators, whoever they may be individually, in terms of any of the manufacturing companies, are less committed to the challenge necessary to bring about the optimum reduction, particularly where the manufacturing base is located in Ireland. There is a general conversation, which one hears in the corridors of this institution, that there is a fear that the inward investor manufacturing companies would pack up their tents and leave with a consequent loss of hundreds of jobs. It is said regularly and across all political opinion. Will Mr. Goodman address that to try to restore people's sense that such is not the case and that we are not being bullied into accepting less than we should? I leave that as it stands.

I wish to ask Mr. Barry about other important initiatives that Mr. Goodman referred to in his contribution, one of which was more rational prescribing. Will Mr. Barry elaborate on that because it is something that I have raised before? I have no doubt we are all conscious, and I am conscious even in terms of my extended family, of a bathroom cabinet overflowing with unused prescribed medications. I cannot attribute it to a particular age profile. It is difficult to know. I have not done any examination or exercise to try to suggest that it is particular to any age group. We are talking about a reduction in drug expenditure through more rational prescribing and I would like Mr. Barry to advise the committee of what is being done in that case. I mean no criticism of those in general practice but I think there is a need to ensure that prescribing practices are as required and on the basis of certainty of being used. I will leave it at that and I appreciate what further the witnesses can tell us.

I thank Mr. Hennessy for his contribution. I am glad he stuck to the opening pages because it runs to many pages and it is a lot of information. Why do we take the average of the nine EU member states? Why do we go for the average? Why do we not take the least expensive? Who has determined that we must take the mean or median position across whatever number of states, even if it happens to be nine? Why is it always that we are last? Why would we not be first, especially when we are such a manufacturing base? I may be corrected if I am wrong, but in respect of new patented drugs manufactured in Ireland, we were basing our cost on what it was costing in other EU member states. Why were we not the first one determining the cost? It follows on from what Deputy Billy Kelleher was asking earlier. Why are we always waiting for three or more of these? Why can we not move from the median to the lowest cost across three or up to nine other EU member states? What do we have to do to be able to say we have

a position and are firm and emphatic on it, end of story?

I am concerned about the sentence in the submission that under the 2012 IPHA agreement, where a medicine satisfied a cost-effectiveness threshold of €45,000 per quality adjusted life year, the medicine progressed to reimbursement. My sense of cost-effectiveness does not equal a threshold in terms of monetary cost alone. Cost-effectiveness is not about a threshold of cost in euro and cent. It takes into account the situation of the dependent patient, the need of the individual citizen, his or her circumstances and availability for work. Where a patient is dependent, it might be that he or she could be a contributing taxpayer if he or she was able to return to work as a result of access to a prescribed medication. I will not go on about it, but the witnesses know exactly where I am coming from in this regard. It seems a very bald statement to refer to a cost-effectiveness threshold of €45,000. It is not what I have understood cost-effectiveness assessments should be.

On the Alexion situation, the Chairman indicated something at the outset in terms of our private meeting earlier. This is the public opportunity. I reaffirm what the Chairman said. It is not lost. I do not know if anyone in the media is taking any interest in our work here but it is important that it is noted that today we decided for the third time to write to Alexion to record our collective Government and Opposition vexation at its refusal to come before us on the cost of eculizumab, known more commonly as Soliris. It is infuriating that a company would take such a rigid stance of refusal on the two previous occasions we have invited it to come before the committee.

I may be the person here living closest to the Border, where I was born and brought up all my life. I am only four miles from it. I am still meeting constituents who drive the short distance north of the Border to get their prescriptions processed. It is still cheaper to access prescribed medications north of the Border than it is in this jurisdiction and, identifiably, to access medications and drugs that are actually manufactured in the State. I ask the witnesses for their comments.

Senator John Crown: Before I start, I note that I would like to meet Deputy Ó Caoláin after the meeting to give him my prescription for Atorvastatin. If one of his constituents could pick some up for me, I would be very grateful.

One of the underlying realities of pharmaco-economics is that we are working in an increasingly globalised world. We hope that as more harmonisation of drug purchasing policy takes place in the EU, it will improve our negotiating position with the companies. I say that with the caveat that we do not want to harmonise down to the UK level and that perhaps the German way of taking new drugs on board is more realistic. In reality, a small economy like ours is not that important. At a global level, if a company reckons it will completely lose sales in Ireland in acting to avoid an adverse judgment against its pricing policies, it will pay that price. We are a tiny part of the international drug trade. With respect to the question of sweet deals, I believe firmly and have for a long time that there is a complete lack of linkage between where international companies put their manufacturing plants and our domestic drug consumption policies. It is all about the 12.5% corporation tax rate. If we ever want to do the experiment to isolate the effect of the 12.5%, we should jack up the tax rate and see what happens. It is possible, however, that companies would try to lead us to believe there were such sweet deals in an attempt to strong-arm us. We discussed this the other day but we saw evidence of it last year or the year before when pressure was brought to bear on the Taoiseach on the issue of the approval of some drugs by companies suggesting darkly, and entirely inaccurately, that it had an influence on where companies decided to locate their manufacturing plants. I hope that as the EU gets better at this

activity, we will be part of a market force which allows us to drive a harder bargain collectively.

My second point is that the companies are now engaging in predatory pricing. There is no way around that. We discussed this earlier in private session, but I recap the point. Companies are no longer basing their pricing policies on cost plus cost of failed drugs plus a reasonable profit margin. Rather, they are using professional marketers to set the price their analysis indicates will be the maximum price the market will sustain before the demand for the drug goes down in line with the principle of price elasticity of demand. We must understand that, unfortunately, we are getting into an adversarial position *vis-à-vis* the companies. The western economies of the USA, Canada, the EU, Australia and others must get together to give companies signals that there are certain thresholds beyond which we will not go on the pricing of drugs. There is an illustrative example of this. A good friend and colleague, Dr. Lenny Saltz from Memorial Sloan Kettering, who trained with me many years ago, reacted to a very unreasonable pricing demand made for a drug called Zaltrap, a colon cancer drug. He said that the incremental difference it made was so small compared with the standard treatment, which in truth was not that great either, that he would not pay for it. The company heard him and the price of the drug was decreased by approximately one third in the USA. That tells us the power of what one can do, but it also tells us that these guys are still making money at a price that is one third lower than the price at which they originally pegged the drug. There is wriggle room on most drugs. In fact, there is wriggle room for most. I know of one drug which has been approved for an uncommon cancer. The company argues that as it is uncommon, the market is not very big. It is €120,000 per annum for the drug. The registration trial for the drug involved 100 patients, which means it did not cost that much money to develop. It is a further example of predatory pricing.

We must make savings where we can because there are places where we cannot. Unfortunately, our market is so small that we are not in a good position to drive hard bargains with international drug companies for expensive drugs. I hope this problem will be addressed at a global level. When I speak to the industry I tell them they are going to kill the goose that lays the golden egg. In a previous generation, one could go to the US Food and Drug Administration with a drug that had a 5% survival advantage in a cancer and be reimbursed and paid for it. That will change. In an era when multiple drugs produce small marginal benefits, people cannot afford to pay for them all. The industry needs to find a way to make those drugs cheaper or apply them to the smaller number of patients where the impact is greater. What can we do? In the short term, we have to make generics mandatory to save where we can. I am happy to take two generic drugs, which I do. If one wants the branded drug, one should pay for it. If society is paying for the drug and has deemed that the generic is just as effective as the branded version, why should it be asked to pay for the more expensive one? We need to find a way to save money on those drugs which make up the bulk of our drugs bill. The bulk of our drugs bill does not relate to the small number of patients on high-tech drugs. It involves the antibiotics, antidepressants and, like those I am on, cholesterol drugs many people are taking.

From a health economics point of view, we have to understand one other reality. There is a bigger picture here. We must look critically at how we spend money on health care. Drugs are an easy target. One of the reasons drugs are an easy target is that people like me who do trials with drugs generally report our results meticulously. One can see in black and white that drug A gave a person three months and drug B gave them seven months. Health economists can then calculate what it costs to get that additional incremental benefit. There are many things we do in medicine which are never subjected to that kind of analysis, and which are done very inappropriately. I will not go into all the details. There are many operations that have limited

impact. There are many people in intensive care unit beds when it is not in their interest to be in that unit and where not only are resources not being used efficiently but also the patient's health care is not being managed appropriately from their own perspective. In looking at figures such as the cost per quality year of life saved, it is critical that we think a little about it.

If one looks at something like cancer care, which in Ireland was historically pretty miserable and is pretty okay now, the one thing we had was good access to cancer drugs. The last problem we needed to fix was the over-prescription of cancer drugs, because we were under-prescribing drugs. There are countries that combat the over-prescription of cancer drugs very efficiently and they have the worst cancer survival rates of major developed countries. The UK has one of the worst cancer survival rates of any health service of equivalent size and sophistication. In New Zealand, no attempt is made to get most new drugs approved. It is important that we not look at problems like cancer drugs in isolation and that we understand that they are a very easy target when attempting to contain costs.

Senator Colm Burke: While I agree with the witnesses that the cost of drugs has come down, I am still concerned. I gave the example last week of someone who comes to my clinic in Cork. He is in receipt of an old age pension, he does not have a medical card and he has had two heart attacks. He travels to Northern Ireland, from Cork to Dublin to Newry, once every two months and is paying less in Northern Ireland for two months of his medication than he would for one month in Cork. I am concerned when I hear that. It is a genuine case where someone is slightly over the qualifying criteria for a medical card, he does not have a huge level of income coming into the house, and his wife does not qualify for the old age pension as she is not over 66. They get the additional allowance for her, but it is still much cheaper for him to travel to Northern Ireland to buy medication. I am not talking about travelling from Dublin or Monaghan but from Cork. That concerns me.

I will go through the figures presented on the €1.5 billion savings since 2006 that the witnesses mentioned. The Oireachtas Library and Research Service presented figures to us showing that savings of €765 million have been made since 2006. It gave a breakdown. In 2006 to 2010, €250 million was saved; in 2010-2011, another €250 million was saved; in 2013, €120 million was saved; and in 2014, €148 million was saved, giving a total of €768 million. We are being told here that it is €1.5 billion. I am a bit concerned about the presentation of figures. The current expenditure level for 2014, according to the witnesses, is €1.92 billion. Again, the Library and Research Service tells us that the total 2012 PCRS expenditure was €1.92 billion. We are, therefore, coming up with the same figures in a two-year period. We might go through the figures a little more closely in respect of where we are making savings because I am not convinced that we are making the inroads we should.

It was mentioned that the figures for generic drug use are now up to around 68% for the fourth quarter of 2014. We were told last week that the figure was 48%. Why are we getting all these confusing figures on generics? It was the pharmaceutical industry itself that made a presentation to us last week saying that the figure for generic usage was 48%, but we are now talking about a figure of 68%. Perhaps we might get some clarification on this.

The other issue that was raised goes back to the ESRI report in 2013. When we talk about the negotiating price, we are talking about the basket of nine countries and we are coming out with the average. Deputy Ó Caoláin asked why we cannot be the lowest of the nine, rather than the average. We are not making enough progress on this matter. It is a huge cost factor. The Library and Research Service refers to the overall cost in 2012. Total PCRS expenditure for all schemes was €2.56 billion in 2012. Those are the figures the service is giving to me. We seem

to be getting different figures from different people. I want to see by the end of 2015 some real change in cost. I am not convinced we are making enough progress in this matter. Legislation was brought in on the use of generic drugs and we are making substantial progress, but could we make much more progress and do we all need to do much more, from hospitals to general practitioners across the board? Are we doing enough and can we do much more? It is not that we do not want to use the money for health, but we could use that money far more effectively in other areas if we could save on the cost of drugs.

Deputy Catherine Byrne: I agree with Senator Burke and Deputy Ó Caoláin. I still have neighbours, families and friends crossing the Border or going to England to get cheaper drugs, or coming back from Spain with drugs they cannot even buy in this country without a prescription. That needs to be addressed quickly. I heard Senator Crown speak before about generic drugs, but why are patients less willing to take generic drugs? Is there any evidence that when patients are on generic drugs there is a longer recovery time? That is what I hear. I am only going by family and friends. When they are on generic drugs it takes them longer to get better.

I love listening to people speak on television about medical science, new cures or people having an opportunity to live longer if they have cancer, arthritis or something like that, but I get nervous when I see figures such as that in six years time, 40% more people in this country will be over 65 and people are going to live longer. They may live into their 80s, but will they be healthier? Research shows that perhaps they will not. My mother died at 89. She had a great life. She was never in hospital, except for in the last six months of her life when she had dementia. We took her home and we had her at home for most of the six months. One thing that struck me was that this was a woman who had lived a long life, had a large family, who had worked at stages of her life and yet was not there at all in the last few weeks of her life. She was just somebody lying in a bed whom none of us knew and who did not know any of us. I wonder about the quality of life people have when we produce medication that makes them live longer. Everyone wants to see family members living longer, but they must have a quality of life. There must be meaning for them in living longer, and it is very sad when their quality of life no longer exists. Why sustain that natural process of life? I am not a medical doctor, but one of my favourite songs is "Who Wants to Live Forever". There is great meaning in that. I see someone putting up his hand. He wants to live forever. I do not want to live forever. I want to have a decent life in order that when I come to its last stages, I am still able to do little things for myself, even though they may be simple. Living longer and not having a certain quality of life serves no purpose. I might as well be honest.

Mr. Fergal Goodman: I have a couple of general comments to make in response to the issues around the agreements. HSE colleagues will be able to pick up on many of the other issues. As I alluded to at the outset, I am not so long in my current post that I have been present through the negotiation of the previous agreements with the pharmaceutical industry. However, all the officials present take their instructions from the Minister for Health and the Government. The Minister is quite determined to continue to achieve further savings in pharmaceutical costs in order that we will be able to respond to the demographic pressures about which we spoke in terms of the emerging new drugs.

When one talks about previous agreements, how hard people drove at them and the question of how successful we were, one needs to recall that an agreement, by its nature, is the outcome of negotiations between parties with competing positions. Therefore, to reach any agreement, be it in industrial relations or any other business-type context, there must be a compromise, presumably on both sides, somewhere along the line. Thus, the parties reach an agreement that

delivers a result for each. Obviously, successive agreements have delivered further benefits and changes incrementally. A current agreement is due to expire towards the end of this year, but consideration is already being given to the objectives and details of what we will be seeking in successor talks. I do not particularly want to elaborate on them today because we are formulating positions.

The other factor that has changed on this occasion is that we now have the benefit of the 2013 Act which gives the HSE significant statutory powers regarding price adjustment. Where it is not deemed possible to reach an agreement through negotiation that is acceptable to the State side, we have the option of using these powers. Obviously, the preferred approach is negotiation. The term "agreement", by definition, represents agreement between parties with a compromise. We are quite clear on the instructions we have received from the Minister. They are quite clear and very much focused on the benefits for the health service, particularly on maximising what we can do with the health budget provided for us by the Government and the Oireachtas.

Mr. John Hennessy: There were quite a few questions and some key themes which I will try to address with the help of my colleagues. They concern the basket of countries used in making a determination on price. I will ask colleagues to address that issue. The cross-border issue was raised in quite a few of the questions asked. Issues of currency arise in that context that I believe we will be able to deal with and clarify. Professor Barry will address for members the prescribing patterns, the use of generics and the quality adjusted life year issues.

I will go through the list of questions quickly and ask colleagues to comment, as necessary. I will begin with Deputy Billy Kelleher's questions on why savings were possible or even achieved in the period after 2006. There are a number of key reasons. First, there was exponential growth in costs from 2004 onwards. Much of this growth was attributable to a population increase and new products and also the expansion of eligibility. That was the period in which the over-70s became entitled to medical cards automatically. This gave rise to a considerable additional cost.

A factor to which I am sure colleagues will be able to allude further was early adoption of new products in Ireland as part of the nine country basket approach. The approach is subject to the original agreement of 2006. I will ask Mr. Flanagan to speak about who decided on the nine countries and why they were decided on.

I understand Soliris is available, but colleagues will confirm this. I believe there were four additional patients registered on it. Obviously, we are still not happy about the price being charged for the product and the process of seeking an improved price for Irish patients continues.

Chairman: Mr. Hennessy might revert to us on the use of Fampyra.

Mr. John Hennessy: Deputy Caoimhghín Ó Caoláin referred to rational prescribing. Professor Barry's programme is getting to grips with that issue. He will be able to allude to it further, in addition to the use of the nine country basket. These are issues that are subject to scrutiny in the context of a new and successor agreement, wherein we would not necessarily be working on the basis of the average. We will be looking for a better approach. Sometimes the pace of adoption has been an influence. Traditionally, Ireland has been one of the early adopters of new products and medicines which, again, reduces the number of countries involved in making up the average. That has now changed, subject to the 2012 agreement and the processes

in place courtesy of Professor Barry's programme.

The quality adjusted life year and the maximum of €45,000 comprise a considerable debating point. The debate is occurring worldwide on health economics. The issue for us in that regard is that the measure is a tool. It is used for automatic qualification of a product. This is by no means the only issue, but it is a useful assessment tool to get business done and products into the reimbursement process. There are obviously bigger picture issues that have to be borne in mind. We saw examples recently of where the cost of products far exceeded the €45,000 threshold. We will try to address the cross-border issue and why drugs are cheaper elsewhere.

Senator John Crown's point on the size of the market was significant. It is part of the bigger picture issue in determining why companies locate in Ireland

Senator Colm Burke raised issues concerning Northern Ireland and the amount saved. We can clarify the discrepancies he is finding in his figures concerning what is reimbursed and total expenditure on pharmaceuticals. Any discrepancy between 2012 and 2014 will be addressed by Mr. Burke.

Generics were referred to. We have an explanation as to why last week companies were citing a figure of 48% and why we are at 68%. We will be able to clarify that issue. I will ask Professor Barry to answer the question on whether there is more we could do on drug prices in securing a better deal for taxpayers. As to why there is a reluctance to use generics, the quality of life issues Deputy Catherine Byrne raised are very important. Perhaps Professor Barry might address the issue of reluctance on the part of the public. It may still feature in respect of generics, but I believe the attitude is changing. We have seen evidence of change in the figures very recently.

Mr. Shaun Flanagan: To respond to Deputy Billy Kelleher's question on the period before 2009 and the changes that have occurred, it is important to note that there has been a series of framework agreements with the industry dating back to the 1970s. Prior to 2013, the HSE or the State had no statutory powers on the Statute Book it could use; therefore, everything had to be done by agreement. If there was no agreement, there was no alternative. To the best of my knowledge, the 2013 agreement represented the first time the State actually legislated and provided powers for the health service to set prices. That changed the dynamic.

On the rationale for using the basket of nine countries, the original basket contained five countries. In 2006 there was a long negotiation. I was not involved, but I understand the negotiators reported directly to a Cabinet sub-committee. At that point it was agreed that the basket would be increased from five to nine countries. Austria, Belgium, Finland and Spain were added and regarded as lower price countries — that is what is coming out in the recent data we have received — than the countries that had been included in the previous basket.

On the subject of the dynamics of the basket, there is no doubt that companies operate a process of what one might call waves of launches. Wave 1 features high price countries and is followed by waves 2, 3 and 4. The first in line are most expensive, about which there is no doubt. That is how companies operate and it is a rational way to operate. Twenty-five of the 28 countries in the European Union operate some form of basket system. To the best of my knowledge, there are three countries that operate what is called a free-pricing market. They are Germany, Denmark and the United Kingdom which are usually in an early wave. The position in the United Kingdom can vary, but the three countries are in our basket. From 2006 onwards, it was recognised that just relying on a basket would result in the same answer all of the time.

This led to the requirement to put in place a health technology assessment process. Therefore, it is not a simple matter of companies coming to us with an average for nine countries and stating this represents the price. That is the absolute maximum price they can achieve. If that is the absolute maximum price they can achieve, they are required to justify the price in the health technology assessment. If the health technology satisfies at a threshold of €45,000 per QALY, it is an automatically important point. It is not a line in the sand above which we will not reimburse. It is an agreed position and, if they satisfy it in their economic dossiers, they are automatically reimbursed.

If they do not satisfy it, we are into pricing negotiations. Those pricing negotiations are commercially confidential and non-transparent. Due to spillover effects into other countries, if the price in Ireland drops, the price in other countries drops. We have pricing reductions that range from 5% to 40% in various medicines. I cannot reveal them because most of the time companies will say they will provide the discount as long as it is regarded as commercially confidential and not revealed in a public forum. That leaves us in a difficult position when presenting to the committee. However, members should be aware that the basket is not the set point. The basket is the starting point and they are required to justify the price and bring it through a full assessment process. Having satisfied the assessment process, the price stands. If they do not satisfy it, difficult negotiations go ahead. As members are aware from recent times, we sometimes reach a stand-off position where companies are holding a line on a price that we feel is completely inappropriate. Where the companies are unwilling to move, decisions must be made on that basis.

With regard to the question on eculizumab or soliris, I can categorically say the reimbursement is progressing. However, the DG said in his press release that there was a screening programme. It is incumbent on the clinicians in question to complete a form, go through the screening process and reimbursement will continue from there. Some patients are through that process and we have applications from four patients. That is the turnover of a relatively quick process. Most of them have been turned around in 24 or 48 hours. If there has not been reimbursement, I assume it is down to the fact that the application form has just been received, has not been received or has not been completed.

Chairman: Is there ongoing engagement with the four people concerned on their applications?

Mr. Shaun Flanagan: Consultants make an application to Professor Barry's programme and it is a relatively simple screening programme. Once they qualify, the consultant will be told that the HSE primary reimbursement service will carry the cost of eculizumab. I know one process patient has been through it and has definitively started therapy. There are four other applications. It is down to people completing forms and getting through the process. There is no attempt to slow it down, in case Deputies have concerns.

I have never been involved in a sweetheart deal, nor have I ever seen one.

Deputy Billy Kelleher: I am sure Mr. Flanagan is referring to the industry.

Mr. Shaun Flanagan: On what Senator John Crown said about companies trying to represent it as such, we are in scenarios where companies enter commercial negotiations and try to say this and after listening to them, we say very politely that it is all very interesting but that the HSE is not entitled to include it. The Oireachtas has directed us in the legislation that the criteria have been set out, one of which is not foreign direct investment. It is not something we take

into consideration, but that is not to say the companies do not include it in letters. However, it is not an issue in a decision.

In terms of parallel trade, Deputy Billy Kelleher made it clear that it was entirely legal across the European Union. If someone wants to parallel import or export, he or she is required to have a wholesale licence. Most countries have elements of parallel trade and in the past when prices were high, this was a parallel importing country when there was an arbitrage opportunity in importing. That parallel exporting is an increasing part of the commentary is an indicator that our prices are dropping and that we are starting to fall below other countries. As recently as 2012, a UK all-party parliamentary group issued a report on difficulties the United Kingdom was experiencing in maintaining supplies of stock as a result of parallel exporting. It is not that this is the only country that has had to consider these issues. As we drive prices lower, it will become an increasing concern. Sometimes a country does not have to be at the bottom of the EU market to engage in parallel exporting. We have become aware of a number of products where parallel exporting has happened and the export country is not at the lowest point in the basket. A country can be unfortunate enough that Germany or the United Kingdom is at a higher level. When this happens and there is a sufficient arbitrage opportunity, specialist wholesalers will export. There is very little can be done to prevent this. We work with the industry in putting in place controls for access to stock and preventing any of these wholesalers from gaining access to Irish stocks. We continue to work closely with the industry on this issue.

The HSE does not buy stock but operates a reimbursement model. We do not own the stock until the day the bill is presented to us - the day after the patient has it. We do not buy stock to be held in a major warehouse; we rely on the standard wholesale and distribution mechanisms the industry has in place to control supply chains. This is consistent with the position in every country in Europe.

Chairman: Is Mr. Flanagan concerned about the supply side, given the remarks made last week?

Mr. Shaun Flanagan: In every reference price decision we make supply is one of the factors about which we are concerned. Why do we not go to the lowest in Europe? The reason is that experience tells us definitively that we will have supply issues. Why do we not go to the United Kingdom in terms of reference pricing? The United Kingdom is at the bottom of the off-patent market. It has been down this road for 30 years and is, by definition, lower than us. We can look good if we go to the United Kingdom, provided we can do the job and get out before the problem starts. In the Health Act there is a statutory requirement on us to worry about continuity of supply. We look at the UK price and every reference price across Europe and try to set a price that is at the average or median figure. I understand it is difficult for people to accept and that it must be very difficult for those who live near the Border. They can cross the Border and get something cheaper, but the United Kingdom is one of the least expensive off-patent markets in the European Union. We must remember that it is a market of 60 million people and that Ireland is a market of 4.5 million. Taking 20,000 packs out of the UK market and exporting them will not be noticed. In Ireland 20,000 packs could be the entire run for the year. As we are very open to losing these supports, we must be careful about it.

Pricing is not the only aspect that drives shortages. There are other reasons, including problems with raw materials, manufacturing difficulties, recalls and quality issues. Manufacturers may also have production difficulties. There can also be industry consolidation and unpredictable shifts in demand, including unexpected increases in demand. Parallel trade and pricing decisions are a minority of the reasons there is a shortage in the market. Most of the shortages

pharmacists experience are not down to pricing and parallel trade issues but to other issues that happen in having a quality assured process. On occasion, regulators must intervene and state there is an issue about a factory. This can lead to a problem with the supply of a particular medicine. It is not as simple, therefore, as pricing and parallel trade. I think I have covered the issue of reference pricing and the United Kingdom.

In terms of numbers, the level of generic penetration must considered whether there is an off-patent market and a patent market. It is technically impossible for a generic to enter the patented market. The figure of 68% we quote is the last quarter reimbursement figure. In the off-patent market 68% of claims we receive are for generics. If we compare it to the figure in the United Kingdom, we must remember that the denominators are different. Senator John Crown may be able to confirm this point independently. Cancer drugs such as sutents are not distributed through the community pharmacy chain but through home care systems and hospitals. They are not included in the UK denominator in terms of UK pharmaceutical spending. They are also not included in the UK OECD figures. They are included in Ireland's OECD figures because we have a different model. We provide these high-tech drugs through the community pharmacy contract network. That means that 90% of high-tech drugs are on patent. By definition, our denominator is bigger; therefore, it is technically impossible at whole of market level, based on OECD levels Ireland produces, to get to 70%. If the committee looks at it where we think it should, which is the proportion of the market where it is possible to compete, 68% of the claims are in generics.

In response to the question about people being uncomfortable about generics, the actual figures no longer bear that out. Increasingly we are seeing, as people become more comfortable with generics and get more used to them, they are becoming more comfortable. Prescribers are a key driver in providing reassurance to patients. As prescribers become more comfortable prescribing them, patients will often take their lead from the prescriber.

In terms of the reference pricing molecules, we are not 90% generic penetration for some. Atorvastatin is 90% plus generic and is the most common statin used. For the one Senator Crown mentioned, we are at 90% generic utilisation. One of the most expensive proton pump inhibitors is omerprazole, which is at 90%. In fact, all the proton pump inhibitors are at or above 85% generic penetration. Reference pricing has made a huge difference and in the generic substitution proportion of that.

Within the 32% portion where there is no substitution, one has to remember the areas concerned. People might be less comfortable about substitution which is something the Oireachtas discussed in detail when passing the Health Act. One must be careful because the further up one goes there are other drugs that one might be less comfortable about substituting.

Chairman: Is the HSE continuing its campaign to educate people?

Mr. Shaun Flanagan: I shall let Professor Barry talk about the medicines management programme. We have continued campaigns on the HSE website. We are also aware that individual companies have media campaigns. The HSE tries to be prudent in the way it spends its money. If it has a big advertisement campaign that costs €500,000, and its message coincides with what we want to say, then it makes sense for us to allow it to spend that money, if it so wishes, and for us to step back. If we need to intervene in the future then we will do so.

We had a campaign for the implementation programme. Our press and comments people were intimately involved in an implementation group. We met loads of groups, including

groups that were vehemently opposed to generic substitution. They seem to have come around in some of the areas. Osteoporosis drugs are now 75% substituted and there has been no evidence of significant difficulty, or any difficulty at all, reported to the Irish Medicines Board or the Health Products Regulatory Authority as it is now called.

I am sorry as I think I have taken possibly too much time.

Chairman: That is fine.

Mr. Patrick Burke: I shall deal with the question on money raised by Senator Colm Burke. I am not going to reconcile the figures here. The figures that have been produced in the Department's material, and in Mr. Hennessy's statement, have come from the published audited figures which are figures that have been worked through with the troika as well. I can provide a summary of those figures.

The Senator mentioned that €2.6 billion was paid through the PCRS. I need to break it down and find out what was included. For example, in 2009 the figure was €2.633 billion but it included €491 million that was paid to general practitioners. As Mr. Hennessy said in his statement earlier, the figure for pharmacy includes ex-factory price, wholesale margin, fees and VAT. It depends on what actor presents what figure and at what point in time.

I can provide the committee and the Senator with a summary that is transparent about the figures we have produced. Then I can take any figure and attempt to reconcile it or let some other actor reconcile it because they may have compiled it in a different way. I hope I have simplified the matter for the committee.

Chairman: I thank Mr. Burke.

Senator Colm Burke: It would be helpful if Mr. Burke was given a copy of the document that I have in order to correlate the figures.

Chairman: Deputy Catherine Byrne has offered her apologies as she cannot be here to listen to the reply to her questions. She will return later.

Professor Michael Barry: In terms of prescribing, it is important for us to acknowledge the huge benefits that medicines afford us. We have seen this in areas such as peptic ulcer disease and coronary heart disease mortality which has experienced a three-fold reduction over the past 25 to 30 years.

The main focus for the medicines management programme is the safe, effective and cost effective prescribing of medicines. Safety is an important element to mention. We must remember that medicines are the most common form of preventable patient injury in the health service. Safety is a big issue for us, regardless of the money which we have spoken an awful lot about today. A lot of our work is advising practitioners on the safer prescribing of drugs. The ones that particularly concern me are the new oral anti-coagulants and we have issued detailed guidance on them to prescribers.

I shall return to the money side of things. Even with reference pricing, there is a significant number of things we as prescribers do but can do better. That has been part of our thrust and I shall give a few examples. In this country inhaled medications for asthma and COPD costs over €100 million every year. I refer to the combination of two inhalers, of steroid plus a long acting beta agonist, which accounts for €50 million a year. There is a new one out, which is 35%

cheaper. Our message to prescribers is very clear - when prescribing one of these new inhaled medications to opt for a product called Bufomix. These are simple things that we can do but we can do better. As Senator Crown has said, we should save where we can. If one looks at statins, proton pump inhibitors, blood pressure lowering medications and anti-depressants, there are 12.5 million prescription items issued for these every year. Can we do better? Yes, we can.

We have looked at each of these therapeutic areas, we are developing them as we go along and we indicate to prescribers what we see would be the drug of choice or the preferred drug. I mean what we would see as the first choice medication. For example, when choosing a statin today one has five choices. We are very clear on the choice that we would advise prescribers to take. We can also highlight the ones that cost us the most. We work down through all these therapeutic areas and we can make significant savings above and beyond what we have heard today about reference pricing. The programme is safe, effective and cost effective and prescribing is what we are all about. We know from the past that this programme has got to be sustained. One cannot just do so for six or 12 months, otherwise people return to their old habits in due course. Therefore, we need a sustained programme to ensure quality prescribing.

The next issue is cost effectiveness. It is important to state that when we talk about thresholds and qualities, we are trying to put a value on the health benefit that a drug will deliver for us. That is where one gets the cost per quality adjusted life. Earlier we heard about the importance of quality of life. That is why we include quality of life in these calculations. It is because one can get a duration of life but the quality of that life is important as well.

I shall now discuss the question of viewpoints. Companies submit their dossiers on cost effectiveness to us, so they put the case together. We will accept a number of viewpoints and one of them is by the health service. As has been rightly suggested, we also accept the societal viewpoint as well which one includes care costs, travel costs, out of work costs, etc. Economic dossiers incorporate all of those factors. In fairness to them, the presentations are of a very high quality. We do capture all of those aspects in regard to the cost per quality of life.

In the vast majority of cases, we do not see any difference in terms of clinical outcomes for generic drugs. It is part of our remit in the medicines management programme to promote generic prescribing and we are happy to do so. It is well accepted that it is not only the most cost effective prescribing but is also safer prescribing. We instill in our junior doctors that generics is safer prescribing. There are many examples that when people read the name of a branded product, they will not recognise it but when they are told the pharmacological name they will recognise it. There is a safety issue in that regard.

Deputy Billy Kelleher: I seek three clarifications.

Chairman: The meeting has run over time.

Deputy Billy Kelleher: I shall be brief. Can a prescribing audit be carried out in pharmacies? Audits would allow us to see trends, for example, of local GPs prescribing expensive drugs. The audit could be done in a general practice. Is an audit carried out on a random basis? Is scientific data pulled from the reimbursement figures?

I wish to mention parallel trading but shall not go into too much detail. If the HSE, the Department or whoever makes an agreement with a company to supply a product at a certain price, is supply guaranteed? Is it just the price that is guaranteed? When one enters a contract to sell something one normally agrees to supply the product as well. I am just wondering be-

cause wholesaling obviously suits pharmaceutical companies. Basically, it is transferring from a cheap to a dear state, so it suits them to have that going. If they are producing a product, would the witnesses not think that in the price contract there would also be an agreed supply contract, which is the normal course in any other business? If I am selling milk, I must supply it at the agreed price.

I am only guessing because I do not know a lot about this but I assume that there are very few launches of patented products in Spain. I am guessing most of them are in Germany and other high-cost markets, or am I wrong? If that is the case, surely that is almost market manipulation in a way. It is a system tied into a minimum of three countries. One launches a patented product and it is in the high-cost country, and it works out from there. Is there any way that the EU or any other organisation or entity could assess or address this issue? That is the obvious one we are all looking at here and which we should talk about.

Deputy Caoimhghín Ó Caoláin: In regard to that matter, I took Mr. Goodman's response as indicating an awareness of this situation and that it will be factored into the new negotiations. All these matters are informing the approach of the negotiators in the course of this year. We must have faith in the negotiators. We have offered our respective perspectives on all of these. We have been taking notes, as have the witnesses. I hope that our highlighting of different areas is of help to the witnesses in their job. We will have to wait and see how good a job they do based on the results that will present. I wish them every success with it.

Chairman: I wish to ask about the availability of the Fampyra drug. We had the community pharmacists here last week to discuss mail orders, so is there any news on that issue?

Mr. John Hennessy: I will ask Professor Barry to deal with the first issue of prescribing audits. Mr. Flanagan will be able to handle the other elements.

Professor Michael Barry: In response to Deputy Kelleher's point, there should be a reassurance that we do audit prescribing. Part of our remit is the ongoing monitoring of utilisation and expenditure across all the major groups. As an example, I highlighted the issue of the new oral anti-coagulants. I felt that was a safety and, indeed, a cost issue. We did monitor the GMS database and were able to examine this and see that there were dosing issues. There were also issues concerning poor prescribed medicines that may not be safe and may increase the bleeding risk. This time last year, this very month, I wrote to all practitioners throughout the country highlighting the issues. We went back to re-analyse the data later and I am glad to say there has been a huge change for the better in prescribing these medications.

Chairman: What was the response to that letter, as a matter of interest?

Professor Michael Barry: It is interesting. One may have thought it would not be pleasant but it was very positive. We got many calls from people who said they looked at their panel of patients and made the appropriate changes. We have seen over 1,150 GPs at this stage and we are getting a positive response from them about prescribing matters. The Irish College of General Practitioners has been excellent in facilitating this. It should come as a reassurance. We are monitoring these and are also monitoring trends in products that may not cost a lot. They suddenly come onto our radar and we then decide whether we need to look at them more carefully, and maybe subject them to health technology assessment. We are looking at it, therefore. It has always been my aim to have an ongoing scrutiny of the pricing and reimbursement of medicines. That is what we are doing now.

Mr. Shaun Flanagan: On the question of guarantees, it is important to point out that it is not actually the pharmaceutical companies which are exporters but third parties in the process.

Deputy Billy Kelleher: It does occur, obviously.

Mr. Shaun Flanagan: No. I genuinely do not think it does because these companies are globalised and they have made predictions of what they will sell into each market. On rare occasions we have had scenarios where, with individual shortages, companies have put two or three times what they were predicting into the Irish market and they cannot keep the stock in the market. That can cause knock-on effects into other countries. These companies have single factories around the world. They have their supply chain mapped out six or eight months in advance. If something unexpected happens in the supply chain, they do try to flex their muscles and move things back into stock.

While we are often in combat with pharmaceutical companies in terms of security supply and people reacting to pressures, in general, our experience is good. Companies genuinely want to ensure their stocks are available, if only because it is bad for their corporate otherwise. If Pfizer has a shortage it is not good for its corporate reputation. These companies jealously guard their corporate reputations, so I would not put any blame on the pharmaceutical companies for being involved in exporting. They do their best to prevent it.

They often also put in place lock-downs on stock where individual suppliers can only get so many packs per month commensurate with what they have bought historically. One will often find third parties in the market complaining about it. The reason for that, however, is that if one had only bought ten packs a month for two years, why does one suddenly need 200? They therefore put locks into their stocks to ensure that people cannot get involved in those processes. There is a sophisticated supply chain operation behind it all trying to control things.

Deputy Billy Kelleher: If one is shifting from cheap markets through parallel trading to dear markets, surely that is going to help the pharmaceutical companies eventually.

Mr. Shaun Flanagan: No, it does not. The Deputy should remember that they have sold the stock into Ireland. Once they sell it into Ireland in the wholesale chain, they have sold it at €10 and no longer own the stock. It has gone into the distribution chain. A third party takes it at that €10 price and exports it to another market at €20. The pharmaceutical company gets no benefit. In fact, if one thinks it through, the pharmaceutical company loses. That is because if it is a higher-price market, they could have sold it in the other market for €15, so it is the third party which benefits.

Deputy Billy Kelleher: The next time in, they are saying that they do not have that.

Mr. Shaun Flanagan: I can genuinely only give the Deputy the benefit of my experience.

Deputy Billy Kelleher: All right.

Mr. Shaun Flanagan: As regards the three, six, nine issue, companies do enter the market in waves. I have explained throughout how we use HTA. I should also probably have said that in 2008, 2010, 2012 and 2013 there were price realignments on the basis of what the baskets were in those countries. Those were many years after the launch. I have no doubt our expectation is that in the next agreement there will be an automatic realignment in various things. In the last agreement the decision was made to take all the savings we can up front, and we realigned everything at the start of the agreement, as opposed to doing it on a phased basis. I

think, however, that in the next agreement there will be an automatic realignment.

The other thing that happens is that when a company makes an application there may well be only three baskets on it. They go through the HTA process and we end up in a commercial negotiation. One of the things we always do is go back to companies and say, "Show us your basket of nine now, guys". Often at that stage one will have seven, eight or nine in the basket. As soon as that happens, one is usually in a better position for leverage.

In addition, while companies submit the basket of three to us, it does not mean that we stop on that day. We have relations with other reimbursement agencies across Europe. When we see an opportunity where somebody has launched at a lower price, that gives us a commercial opportunity to negotiate with a company. We do go back and do that.

Deputy Billy Kelleher: I asked about where products get launched.

Mr. Shaun Flanagan: Products are launched in Spain. In the unpatented market, Spain is not necessarily any cheaper than elsewhere. Companies have very tight pricing windows that they try to apply across the whole of Europe as far as they can, particularly at launch. Spain is not in the first wave but it is one of the earlier wave countries. I am not too sure we have data that are readily to hand.

Deputy Billy Kelleher: They could be launched in Germany, too, I would imagine.

Mr. Shaun Flanagan: Yes, absolutely. There are three markets that are free-priced, in Denmark, Germany and the UK. One can take it that if one is entitled to name one's price in countries, those countries are early launch places.

Chairman: I am conscious of time because we are running over.

Mr. Shaun Flanagan: I have two more questions to address. Will I keep going?

Chairman: Yes.

Mr. Shaun Flanagan: As regards fampridine, that has been a difficult assessment process. We have gone back and renegotiated with the company. We have also re-engaged with clinical specialists. We are working to try to agree a protocol that might allow us to extend reimbursement. The particular difficulty with fampridine is that about one third of patients get a good response, one third get a partial response and one third get no response. Clearly, if one could be certain that one was only paying at a reasonable price for the people who get a very good response, one would be more eager to reimburse. We are trying to work towards that outcome. We are hopeful of progress on that in the near future.

The last question concerned the healthwave type of scenario.

Chairman: Mail order in general, yes.

Mr. Shaun Flanagan: I cannot talk about mail order in general because there is a policy around changing legislation. In terms of healthwave, however, the HSE would welcome any price competition in the market. We have made it clear that we set prices for reimbursement and for the schemes, but we do not set prescription prices. Any competition is welcome but we would want to be cognisant that there is a completely different model. We have a population of 4.6 million with 1,800 pharmacies. If one takes it that the average pharmacy probably covers a population of 2,500 people, such a pharmacy might have 1,000 patients. The Healthwave

model, as reported by itself, involves 10,000 patients paying a fee of €25 upfront. Members can see clearly that it is a different model and there is a choice for society in this regard. If one needs 10,000 people to run that model, then perhaps one only needs one tenth of the number of pharmacies and that is not a model the HSE necessarily would support 100%. I know myself that with children, if one needs a prescription late at night and one is in Cork, west Clare where I am from or wherever, one will want a local pharmacy at which one can get a prescription for that child and get it quickly to avoid a hospital admission. If one is in the unfortunate position of having a family member who is coming home to spend his or her last few days with one and if one needs access to opiates of whatever, one will not be going to a pharmacy in south Dublin with a huge population around it. That model is built on chronic patients with no changes whatever and our pharmacy model delivers a great deal more than does the other type of model.

However, I reiterate there is nothing wrong with competition. We welcome the pricing competition and people can then make their choices.

Mr. John Hennessy: Before the Chairman concludes, I hope we have assisted the committee in addressing some of the questions on this important issue. It is a huge area of expenditure and is of considerable public interest as well. Our approach has seen significant progress because, as the joint committee has heard, a balance must be struck between reducing price and maintaining supply, which is critical. As for the future, a key priority for the HSE is Professor Barry's programme in respect of rational prescribing. One other point I might add is in the area of information and transparency and pertains to providing a lot more information in the public domain on price and costs and helping the debate on this important area through greater transparency on the figures. The points Mr. Flanagan has just made on competition, choice and well-informed consumers are highly pertinent in this regard.

Chairman: I thank the witnesses for their attendance at a lengthy and highly informative meeting. I thank them for their time and involvement.

Deputy Caoimhghín Ó Caoláin: I believe Mr. Goodman also wished to make a point.

Mr. Fergal Goodman: I have one brief point to make on mail orders. We all are cognisant that online purchase of all sorts of services and products now is becoming a reality. In the Department of Health's national policy and regulatory oversight role, it is an area at which we are looking to scope out and ascertain what, for example, is emerging by way of practice in other countries and whether there are things for which we need to forward plan and about which we must think, while highly cognisant of the issues Mr. Flanagan raises in terms of continuity and accessibility of supply. Nevertheless, it is an area at which we are having an initial look from a policy perspective and is something the Minister has asked us to examine.

Chairman: I again thank the witnesses.

Sitting suspended at 11.45 a.m. and resumed at 11.50 a.m.

General Scheme of Public Health (Alcohol) Bill 2015: (Resumed) Alcohol Research Group

Chairman: We will resume in public session. I want to remind people about mobile phones as they interfere with broadcasting of the session. The second segment of our meeting today is to continue our pre-legislative scrutiny of the heads of the Public Health (Alcohol) Bill 2015. I

warmly welcome Dr. John Holmes and Mr. Colin Angus to this committee meeting. Apologies for holding you, as you have seen our previous meeting ran over time, but it was important that we let it run on.

Dr. Holmes is part of the Sheffield Alcohol Research Group which plays a leading role in carrying out key international research to examine the impact of minimum unit pricing on drinking behaviour. Dr. Holmes has spoken on this topic in the Scottish Parliament and in Westminster. I would ask that members give him due consideration and thank him most sincerely for coming before us today.

Witnesses are protected by absolute privilege in respect of their evidence to the committee. If you are directed by the Chairman to cease giving evidence on a particular matter and continue to do so, you are entitled thereafter only to qualified privilege in respect of the evidence. You are directed that only evidence connected with the subject matter of these proceedings is to be given. Members and witnesses are reminded of the long-standing parliamentary practice that they should not comment on, criticise or make charges against a person outside the Houses or an official by name or in such a way as to make him or her identifiable. I invite Dr. Holmes to make his opening remarks.

Dr. John Holmes: I thank the committee for inviting us to give evidence today. As the Chair said, the Sheffield Alcohol Research Group has been conducting work looking at alcohol policies in general and minimum unit pricing in particular since 2008. The Irish Government and the Northern Ireland Executive commissioned us in 2013 to examine the potential effects of minimum unit pricing in their respective countries and we will focus on that work in our presentation today. However, before coming to that, I would like to give the committee a little background on the wider evidence on the effectiveness of using alcohol prices to reduce alcohol-related harm.

A major review in 2009 examined the evidence on the impact of alcohol price changes on alcohol consumption. It found that increases in alcohol prices were consistently and significantly associated with falls in consumption. This was the case for total alcohol and also for each alcoholic beverage such as beers, wines and spirits. We saw the same thing for younger and older drinkers and we saw that binge drinkers were also responsive to price changes. These findings have been replicated across at least two other major reviews. An example finding is that, on average across different times and places, a 10% increase in the price of all alcohol is associated with an average 4.4% fall in consumption.

However, our primary interest is not whether alcohol price increases reduce consumption but whether they reduce the harm caused by alcohol. A further review of 50 studies concluded that indeed they do. Based on the findings of that review, the researchers estimated that a doubling of alcohol taxes in the US would lead to a 35% reduction in alcohol-related mortality, an 11% reduction in car crash deaths and smaller reductions in sexually transmitted diseases, violence and crime associated with alcohol.

Minimum pricing is a specific form of price increase targeting the cheapest alcohol which, as you will see later, is disproportionately purchased by the heaviest drinkers. Therefore, there is good reason to expect it will have an impact on alcohol-related harm. Several Canadian provinces have had this kind of policy in place for many years and recent evaluations have shown that those policies have reduced the harm from alcohol in those provinces. The Canadian policies are not quite the same as minimum unit pricing as proposed in Ireland and the UK, because minimum prices are not directly linked to the strength of the drink. However, the same basic

principle of a minimum price, below which alcohol cannot be sold to consumers, does apply.

The Canadian evaluations have shown that, all else being equal, increases in minimum prices are associated with falls in alcohol consumption, in alcohol-related hospital admissions and also in deaths due to alcohol. The graph in figure No. 1 of the opening statement, which has been circulated to members, shows one example study. The black line is the average minimum price of all alcohol in British Columbia between 2002 and 2009. The grey line is the rate of wholly alcohol-attributable deaths in the province. These are the deaths very closely associated with heavy drinking such as alcohol poisoning and alcoholic liver disease. The graph shows that a sharp and sustained increase in minimum prices in 2006 was swiftly followed by a sharp and sustained fall in deaths closely associated with heavy drinking. This *prima facie* evidence of policy effectiveness was supported by the statistical analysis which estimated that a 10% increase in minimum prices would be associated with a 32% fall in those deaths closely associated with heavy drinking. So there is good evidence from Canada that minimum prices and minimum price increases lead to substantial falls in the harm caused by alcohol, all else being equal.

I will now turn to our own work. We were asked by the Irish Government to estimate the potential impact in Ireland of different levels of minimum unit pricing, MUP, using our Sheffield alcohol policy model, SAPM, as we call it. For a given alcohol policy, our model provides estimates of changes in alcohol consumption, in consumer spending on alcohol, in revenue to retailers and Government, in the rates of various different alcohol related harms, in the costs of those harms to individuals' quality of life and in the direct costs to public services. A key feature of the model is that we do not just estimate these effects at a population level, we are also able to estimate the effects on different groups in the population defined by age, gender, income and how much alcohol people drink.

At this point I will be talking about low risk drinkers, increasing risk drinkers and high risk drinkers. Low risk drinkers are drinking within the Government's drinking guidelines of around 17 standard drinks per week for males and 11 standard drinks per week for females. High risk drinkers, the heaviest drinkers, are those consuming more than 40 standard drinks per week for males and 28 standard drinks or more for females. Increasing risk drinkers fall between those two levels.

The model methodology for SAPM is too complex for this short presentation and we are happy to discuss it in more detail during the questions. The basic idea is summarised in the figure No. 2. The SAPM works sequentially so we first estimate the impact of introducing MUP on prices. We then use those price changes to estimate how peoples' consumption would change. Then we use those consumption changes to estimate how rates of the different harms would change. Finally, we use the changes in the rates of harm to estimate how the costs of harm would change. Although each of these steps involves quite complex statistical work, the methods we use are largely orthodox in scientific terms. What has made our work so influential and impactful is that we look at a very broad range of outcomes, which is unusual for this kind of model. We are also able to look at the impacts on different groups in society and hopefully the committee will see why that is useful.

I will now turn to results. First we estimated the impact of different levels of minimum price on consumption. Figure No. 3 shows that as the minimum price gets higher, the consumption reductions get bigger. This is fairly obvious because one is affecting more of the market if one introduces a higher minimum price. Above a minimum price of about 60 cent per standard drink one starts to get quite large reductions in consumption. At 70 cent per standard drink one

gets a consumption reduction of 1.9%. At 80 cent per drink one gets a 3.8% reduction. At 90 cent per standard drink one gets a 6.2% reduction. For the remainder of our presentation I will focus on a minimum price of €1 per standard drink just as an indicative example.

Based on our modelling, we estimate that a €1 minimum unit price introduced in Ireland would reduce total alcohol consumption by around 8.8%. By the 20th year after the introduction of this policy, when we would expect to see the full effects, that reduction of 8.8% would result in around 200, or 16%, fewer deaths per year, and around 6,000, or 10%, fewer alcohol-related hospital admissions. From year 1 of the policy, and every year thereafter, we would expect to see around 1,500 fewer alcohol-related crimes and over 100,000 fewer days absent from work due to alcohol. A cost breakdown is provided in table No. 1 in the handout but the headline figure is that over 20 years, the total reduction in the cost of alcohol-related harm is estimated to be around €1.7 billion. This accounts for costs to the police and health services, and also a financial valuation of improved quality of life. The impact on retailers is likely to be positive, as minimum unit pricing is not a tax. Money from the higher prices is held by the retailers. We estimate that off-trade retailers, that is, shops and supermarkets, would receive approximately €69 million extra per year from alcohol sales. Although the policy does not directly affect pubs and restaurants because their prices are already higher than the minimum price threshold, we would expect to see changes in consumer behaviour. For example, people who are buying less alcohol in the supermarket might go to the pub more. For that reason, we expect there may be a slight increase in on-trade revenue as well.

Regarding tax revenue, the negative impact on the Exchequer would be modest, as lost duty from falling alcohol sales would be largely offset by rising VAT revenue from higher alcohol prices.

A key feature of the policy of minimum unit pricing is that it does not affect all drinkers equally. The main driver is how much cheap alcohol different groups buy. Low-risk drinkers purchase very little cheap alcohol - that is, one or two standard drinks per week for less than €1 per standard drink - irrespective of whether they are in poverty. Even low-income low-risk drinkers do not buy much of this cheap alcohol. Compare this to high-risk drinkers, who purchase substantial quantities of cheap alcohol. Although high-risk drinkers in poverty buy more cheap alcohol than those not in poverty - 43 standard drinks per week versus 26 - it is clear that those on higher incomes still buy cheap alcohol. It is not just low-income people who will be affected.

The Sheffield alcohol policy model, SAPM, takes account of these different purchasing patterns, and the estimates of annual reductions in consumption for each of these groups reflect this. We estimate that the annual reduction in consumption for low-risk drinkers would be very small; they would be largely unaffected. It is estimated that low-income low-risk drinkers would reduce their consumption by just 25 standard drinks per year, which is equivalent to drinking three fewer bottles of wine per year. That is a small reduction. Compare this to high-risk drinkers, who, it is estimated, would reduce their consumption by well over 500 standard drinks per year for those in poverty and 480 standard drinks per year for those not in poverty. This is equivalent to approximately 60 to 70 bottles of wine per year. That shows the much greater impact on high-risk drinkers.

A concern for some parties has been the potential financial impact on low-income drinkers. Our modelling does not support these concerns. We estimate that spending would fall in most groups. Rather than spending more to maintain their level of consumption, most drinkers tend to reduce their consumption and spend less on alcohol as a result. Spending is only estimated

to increase in the higher-income groups. It is worth noting from the graph that these spending changes are fairly small. The largest reduction is €159, but most reductions are in the tens of euros. When one compares that against how much high-risk drinkers spend on alcohol per year - an average of over €5,000 - we are not making much of a dent in people's alcohol spending. Spending is not the significant factor; it is the pattern of consumption, and who is affected by those consumption patterns.

All research has limitations. Our aim, which we hope to talk about in greater detail, is to be transparent about these and help policy makers understand their implications for our estimates. Some of the key limitations of the SAPM include our assumption that prices of products above the minimum unit price threshold will be totally unaffected. We assume that prices below the threshold come up to the threshold and everything above it is unaffected. This is unlikely to be the case in reality because, for instance, Diageo is unlikely to want Smirnoff to become the cheapest vodka on the market. We are likely to see what we call premiumisation - products being pushed up to assume a certain place in the market. What that means is that we are probably underestimating the impact of the policy. Our estimates are probably a little conservative.

There is a lack of clear evidence for the impact of such policies on the use of illicit alcohol or alcohol substitutes such as illicit drugs. We know from elsewhere that when prices increase we see falling levels of harm, and this suggests that any negative side effects are not sufficient to outweigh the benefits. We do not ignore these limitations and, where appropriate evidence is available, we test the sensitivity of our results to a range of assumptions, data sets and analytical methods. What those sensitivity analyses have shown is that although the numerical results change, the broad conclusions stay the same. There is strong and consistent evidence that price increases reduce alcohol consumption and related harm. Minimum pricing is a targeted form of price increase, as it tackles disproportionately cheap alcohol purchased by heavier drinkers. We estimate that it would not penalise low-risk drinkers, irrespective of income, because they buy little of this cheap alcohol. In contrast, high-risk drinkers buy large quantities of cheap alcohol and would be affected. These conclusions have been found to be robust to a range of alternative assumptions, data and analytical methods.

Deputy Caoimhghín Ó Caoláin: I warmly welcome Dr. Holmes and Mr. Angus, and thank them for their submission and oral presentation. I have already indicated that I will support the Bill, but I have some concerns about minimum unit pricing. I do not wish to be obstructive, but I want to tease out the issues, because I have concerns about the effectiveness of minimum unit pricing and its impact across society. I have some concern for those who are least well off, who I fear may bear the greatest impact. Their general health may improve from drinking less. Even in the submission we heard on Tuesday, I had a sense that there was a targeting of those on lower incomes because of the expectation that the statistics will show greater improvement from the targeting of this group of people. I would like to see the targeting equalised because I do not believe that alcohol abuse is the reserve of those who are least well off in our society. I am cognisant of the cases I know personally of people who are very comfortably well off but are in difficulties because of abusing drink.

It is interesting that Dr. Holmes referred to research in the US that proposes to double alcohol taxes in the United States. I am not opposed to increasing the cost of alcohol, but I have argued consistently that we should look at increasing the excise duty on alcohol per unit measure right across the board. This would have a greater impact across the board. Contrary to what was said in the presentation - I mean no disrespect to retailers such as shops and supermarkets - we should take alcohol sales out of these settings. It is inappropriate that, as Dr. Holmes has

acknowledged, shops and supermarkets will make some €69 million extra from alcohol sales on the basis of €1 minimum unit pricing. This is from what has been put on the record this morning. I argue that if we were to increase excise duties, that €69 million would be in the public purse and could be employed to address the consequences of alcohol abuse not only in direct assistance for the abuser but for those who suffer most as a consequence of alcohol abuse. I am particularly mindful of the fact that the incidence is greater among men, so I refer to wives, partners and children or those in immediate contact, who can suffer inordinately.

I have put this argument all along, but I concede that I have not won it, as the thrust is going in the other direction. I am giving everything I can if it will be of benefit. My concern is that we could better utilise this money if it were ring-fenced for the purpose I describe. In this instance, we will see greater profits created, and I am not convinced that we will see such a significant decrease in sales of products. Diageo in Ireland, for example, will have very little to fear. I would prefer for these companies to be worried, but they are not. That also applies to other manufacturers and those international companies which sell their products here through various outlets. Will the witnesses comment on some of the points I made? I have not posed them as direct questions but I am giving a view on the matter.

Will the witnesses comment on who would be affected by minimum unit pricing? I get the sense that the witnesses are concurring with my view when they indicate that minimum unit pricing does not affect all drinkers equally, as it will not. I have traditionally been a voice for those who are more marginalised and are from lower to middle-income backgrounds. I am concerned because they are not all alcohol abusers. We should make no mistake about that. Nevertheless, for the vast majority, this will have a deleterious impact on their weekly financial condition. The delegation has indicated that those on higher incomes are still buying these products and will be affected by the policy. That is true for those who buy these products, but it is not a case of equal impact.

I thank the witnesses for coming here and giving their insight. I wish both of them well.

Senator John Crown: I welcome the witnesses. In my day job I do a bit of biomedical research, and it is very nice to hear a really professional and top-quality research-based presentation in these halls. I have a couple of quick questions. I may have missed the witnesses mentioning the average price of a unit of alcohol purchased in Ireland now. Do we have some idea of the quartiles and what percentage of units of alcohol are purchased for less than 50 cent, between 50 cent and 75 cent, etc.? I presume the delegation's expertise extends to comparative research and other strategies for reducing alcohol consumption. Are the witnesses aware of anything else that has worked as well as this? Is there any other strategy of alcohol control across society that has worked as well as pricing?

We have had a bit of chat in this committee about the antics of the tobacco industry and a fair bit of discussion about pseudo-science and so on. Have the witnesses encountered much disinformation funded heavily by the industry which attempts to discredit their research? Will they give advice on how to handle that? Getting to the question of price elasticity, do the witnesses have any sense that there is a ceiling effect beyond which one would be dealing with compulsive or addiction-driven drinkers who will not be price-sensitive in their demand for alcohol? I commend the witnesses for their great research and wonderful presentation.

Deputy Peter Fitzpatrick: I welcome the delegation. There are three categories of drinker, and, as a non-drinker, I believe it important that people realise there are such discrete categories. It was stated that low-risk drinkers are males who consume fewer than 17 standard drinks

per week or females who consume fewer than 11 standard drinks per week, or an average of two drinks per day. People may think that two drinks per day is not a terribly high figure. The next category is that of increased-risk drinkers - males who consume between 17 and 40 drinks per week and females who consume between 11 and 28 drinks. Again, many people might not believe three or four drinks per day is a high figure. The alarming category is that of high-risk drinkers - males who consume 40 or more drinks per week or females who consume 28 or more drinks per week. That amounts to five or six drinks per day, and the witnesses have estimated that this would cost a family €100 per week. I believe that the minute a person takes his or her first drink, he or she becomes a low-risk drinker.

If a minimum price regime came into effect next week and brought about a 10% increase in prices, how long would it take to affect alcohol consumption? It was stated earlier that if alcohol prices were increased by 10% across different areas there would be a 4.4% decrease in consumption. Would that happen in Ireland? How would we know if the process works? This will affect supermarkets and off-licences. How will we know if these businesses sell below the set price? The Canadian Government's initiatives were mentioned, but have the actions of any other countries been studied? What level of success is there in other countries? Why are some countries successful while others are not?

It is estimated that in Ireland, 1,500 hospital beds are taken up every night by patients experiencing alcohol-related harm. Alcohol consumption in Ireland has doubled in the past 50 years. We badly need to address the major problem we have with alcohol in Irish society, especially the availability of cheap alcohol to underage and young drinkers and those who binge drink or drink hazardously. My main concern is the health of drinkers, who may suffer liver diseases, and the safety of families. Not a day or a week goes by in which I do not have men, women and children coming to my constituency office to tell me about alcohol-related problems. Apart from minimum unit pricing, what other action could be taken to reduce the consumption of alcohol, especially for high-risk drinkers?

Senator Colm Burke: I pay tribute to the delegation for their fantastic presentation, which has been very well researched. I agree with previous speakers in that it is a very valuable document and we must take it very seriously.

Our attitude towards drinking was summed up to me in the past week when I spoke to somebody who had returned from holidays. Half an hour into the flight, the crew of the aircraft asked for medical assistance from among the passengers, and when a medical person went to help, it turned out that the person requiring help was a passenger suffering from withdrawal, as that person had been drinking at least 14 units of alcohol per day on holidays. This leads me to my question. I agree fully about minimum pricing, but what needs to be done in addition to that? I am thinking particularly about what needs to be done to educate young people when they are starting off in college. There is a university and an institute of technology in the area I represent. I have seen a huge change in drinking patterns over the last ten years. Young people are now buying drink, particularly spirits, to consume in their own apartments. The disadvantage of that change is that there are no measures when one is drinking in one's own apartment. On the basis of their experience, what do the witnesses consider to be the best way to transmit information to young people? What changes would they make in this whole area? Do they believe there are no changes that can be made? Is there evidence from other countries of how drinking among young people was dealt with? When young people start in college, it is the first time they have real freedom, especially if they are staying away from home. It is an extremely important time as regards getting the message out. Their behaviour during those years can set

the pattern for the rest of their lives. Does the research group have any evidence of how other countries are dealing with that? How have they tackled it?

Senator Jillian van Turnhout: I join others in thanking Dr. Holmes and Dr. Angus for coming here today and for the report we received yesterday afternoon. We have done our quick read, but we have not read it in detail. I will certainly give a lot more time to it.

The questions raised by Deputy Ó Caoláin are probably ones we are going to be hearing more of as we go through the legislative process with the public health (alcohol) Bill. They would have been to the fore in my head when I first came to the issue of minimum unit pricing. I was happy to read the fifth conclusion in the research group's document, which relates to the health effects of this measure on those in poverty. We need to strike a balance between those effects and the other impact this measure might have.

Senator Crown asked about the ceiling or tipping point. How do we determine where we set the minimum price? It might seem very compelling to say that if we keep increasing the minimum price, we will save many more lives. Where is that point? How do we determine where to set the price? When we are looking at the legislation, how best do we ensure we set the price appropriately?

Dr. Holmes referred in his presentation to "premiumisation", which is the idea that the drinks industry will increase the price of its products to ensure its brands retain a premium status. Could this mean that people will switch to cheaper alcohol? Has the research group looked at the effects of that? How can we be sure the consumer will be protected? If a minimum unit price is set, and we see general prices going up over time, how do we ensure that price is appropriate for the marketplace as time goes on? Does it have to be linked to something? I can understand what will happen on day one. How do we provide for a system that is sufficiently robust?

Senator Crown spoke about misinformation. It is excellent for us to have the evidence that has been presented here. I note the point made by Dr. Holmes about illicit drugs. This is one of the main themes in the correspondence I have received on this issue. It has been suggested that minimum unit pricing will lead to an increase in people taking drugs. It seems from the research group's presentation that there is no evidence to support that at the moment. There is no basis for somebody to put forward that proposition. If the witnesses could give us any more information on that, I would welcome it. I imagine we will hear more and more about this argument.

Did the research group look at any parallel strategies when it was doing its study? Senator Burke spoke about education. Does this have an effect? Dr. Holmes referred to the experience in Canada. Did the drinks industry there oppose the approach to minimum unit pricing that was taken in Canada? Maybe they could give us some information that would help us to understand that. We know that the drinks industry in Scotland is taking an ongoing court case against minimum unit pricing. To me, that is another reason we know it works. Maybe that is just me being me. I would be interested to know what kind of evidence or so-called evidence - "misinformation" is a much better word to describe it - they are putting forward.

Deputy Catherine Byrne: I apologise for not being here for part of the meeting. I had to go to my office to meet somebody. I have read the research group's document and I listened to Dr. Holmes's contribution on the monitor in my office. I have three or four questions. This committee receives many documents. This is very much an evidence-based document. I have

to say it is one of the most interesting documents I have read in a long time. It highlights many different areas about which we might not have not thought previously, which we will have to look into. If the questions I am about to ask have already been asked, I apologise and ask Dr. Holmes and Dr. Angus to skip over them.

Do the witnesses believe minimum unit pricing will bring people back towards social drinking in local pubs and restaurants? There is a feeling among a certain cohort that if something can be done to increase the price of alcohol, it might encourage people to drink less at home and bring them into more controlled social surroundings. Do the witnesses believe minimum unit pricing will reduce the consumption of alcohol among those under the age of 25? Do they believe people in lower socioeconomic groups will reduce their consumption of alcohol if minimum unit pricing is introduced, or will they continue to drink as they do at present? The document provided by the research group shows that people in these groups drink an average of 43.2 standard drinks per week. Will they continue to drink at home or will they go to the local pub? Do the witnesses believe education plays a role in giving young people an opportunity to understand the serious health issues that are associated with drinking alcohol? I refer particularly to binge drinking among young teenagers. I apologise if some of my questions have been asked already.

Dr. John Holmes: I will answer some of the questions that have been asked. My colleague, Mr. Colin Angus, will respond to some of them as well. An overarching point that applies to pretty much everything that has been said is that there is no perfect alcohol policy. Minimum pricing is not going to solve every problem. When I read through the heads of the proposed public health (alcohol) Bill, I was encouraged to see that the Government is taking quite a comprehensive approach. Something similar was done with the alcohol strategy in the UK, although it was eventually gutted. Not much that was effective was left in the end. The key thing is that minimum pricing should not be considered on its own. The question of what minimum pricing will do should be considered alongside the question of what other policies will do. What does the Government's policy strategy as a whole achieve? Does it hit all the different things the Government wants to hit? Deputy Ó Caoláin made the point that minimum pricing is particularly effective because it targets the very high levels of consumption of very cheap alcohol among low-income, high-risk drinkers. We need to be very precise here. We have examined this issue in the UK. We had a paper published in *The Lancet* last year looking at this in particular. We need to be careful not to make sweeping statements. It is not that minimum pricing will target the poor - it is that it will target low-income drinkers who are consuming at very high levels. Low-income drinkers who are consuming at low levels will be largely unaffected because they are simply not buying much of the cheap alcohol that the policy affects.

Deputy Ó Caoláin made the relevant point that low-income drinkers who drink at high levels are still low-income drinkers, or people who are financially constrained. I would respond to that by mentioning that the evidence we have on how alcohol harm occurs suggests that a person with a low income or of a low socioeconomic status suffers a greater risk of harm for each drink he or she consumes than an equivalent person of higher socioeconomic status. A low-income person who drinks 30 units, or standard drinks, per week is at greater risk than a high-income person who drinks the same amount. If we want to tackle the harm caused by alcohol, to a certain extent we have to target the low-income heavy drinkers because they are the people who are experiencing a lot of the harm. We need to ensure we go about that in an equitable way that does not aggravate other problems. We would argue, on the basis of the evidence we have gathered, that minimum pricing seems to do that. It seems that people would respond to these price increases not by spending a greater percentage of the family budget on alcohol

but by reducing their spending on alcohol, reducing their alcohol consumption and improving their health as a result. I agree with the suggestion that has been made that this improves the well-being of those around these people as well. I guess that is my main response to that.

The question of how people are affected by this is a little more complex than it might come across in the service level and in my short presentation. While people from all social backgrounds are likely to be buying some alcohol affected by this measure, not all alcohol products are affected equally. There is a threshold and some alcohol products will be a little below the threshold, while some will be a long way below it. Lower risk drinkers tend to drink a little of this alcohol. The higher risk drinkers are the ones who are buying this alcohol which is very cheap. They will experience some big price increases. This has to do with how alcohol is sold because if one is buying large quantities, one can buy it at much cheaper prices per standard drink. The same applies if one is buying cheap spirits which is only bought regularly by heavy drinkers. They buy certain products which are only bought regularly by those drinking at risky levels.

Tax was raised as an issue. A key point is that tax should not be seen as an alternative to minimum pricing. They should be seen as complementary strategies. If members want to tackle heavy drinking among higher income groups - they should want to do this - tax may be a better targeted option. However, there are some problems with it. The way alcohol is taxed is not fully within the Government's control; it is partly under the control of the European Union. For example, a bottle of 10% strength wine will cost less per unit than a bottle of 14% strength wine. This is because the European Union specifies that wine must be taxed by volume, not by alcohol content. The same applies to cider. One of the reasons we have very cheap high strength cider in the United Kingdom is we have very low taxes on it and also the tax rate does not increase as the alcohol gets stronger. One of the recommendations I make to the committee in the long term is that the Government make the case in Europe for alcohol to be taxed based on the strength of all products. This would allow a much more rational and health-focused taxation system. The UK Government is also looking at this issue.

Mr. Angus will talk about price distribution.

Mr. Colin Angus: I will add a comment on tax. If members imagine tax as an alternative to minimum pricing, there are issues of targeting in the sense that they would affect all of the alcohol products everyone is buying, not just the very cheap alcohol favoured by the drinkers who suffer the most harm. We recently published some research which looked at the way retailers responded to changes in tax. It shows that they did not just flatly increase the price of all products in line with what we all expected following the tax increase. In the case of very cheap products they increased the price by less than we would have expected and over-shifted onto expensive products. Retailers are doing what members do not want them to do. They are increasing the price of the alcohol they want to affect the most by the least amount and increasing greatly the price of the alcohol in which they are less interested because it is very expensive and not drunk by the drinkers suffering most of the harm.

Dr. John Holmes: It also loads an extra cost onto moderate drinkers who are buying slightly more expensive alcohol and paying the extra cost involved to subsidise cheap alcohol for heavier drinkers.

A few members asked about other policies that might work and how they might fit in a wider strategy. As I said, a broad strategic approach is needed which touches a wide range of bases. International evidence suggests pricing is one of the most effective ways of tackling the issue

of the hard caused by alcohol. The way it is implemented is clear. The effects are consistent in that it tackles both consumption and harm, but that is not to say pricing is the only option the committee could consider.

A few members mentioned education. Education is important, but the evidence suggests that on its own it will not reduce problem drinking because there are too many other influences on the reasons people drink. There is too much advertising which shapes alcohol as a desirable product and appeals to young people in certain ways, while there is too much cheap alcohol available. Therefore, the level of availability is too high to say education will solve the problem. However, we do need to teach young people about the dangers of alcohol, but that education might be more effective if the system in which alcohol was retailed and promoted was got right first. It is, therefore, about having a comprehensive strategy.

There are proposals before members on the labelling of products. There is not a great amount of evidence that it will reduce consumption, but there is evidence that it will increase consumers' understanding of the risks associated with drinking, It should knowledge of what is contained in the alcohol and specific risks such as drinking during pregnancy. This is more likely to affect behaviour if the influence on behaviour of cheap alcohol and advertising was reduced. There is also a point to be made about consumer rights in that people have a right to know what they are drinking.

With regard to the industry and disinformation, we have experienced a good deal of this. Members raised questions about the way the industry had responded to this policy, which is supported in Canada. I am not sure if it supported it when it was brought forward several decades ago, but it generally support it because it makes it money, as we have discussed. However, in the United Kingdom the off-trade retailers who will be most affected are strongly opposed to it because they do not want alcohol sales to be regulated. We suspect that they know this policy will have an impact and it will impact most on the heaviest drinkers. The top 10% of drinkers in the United Kingdom consume 30% of the alcohol drunk, while the top 30% consume 80%. When we talk about the industry selling responsibly, it makes a huge chunk of its profits from those who drink alcohol above what is deemed to be the responsible level. It is, therefore, in its interests to ensure policies which regulate drinking or seek to reduce heavy drinking are not implemented.

Chairman: Does Dr. Holmes believe these measurements are consistent with the way in which we should measure our alcohol consumption?

Dr. John Holmes: That is a difficult question. The point in setting out units is largely to help the public understand the quantities they drink because drinks have different strengths and the problem is that they generally do not know the strength of what they are consuming. It would be helpful for consumers if unit or standard drink information was placed on products. If it were placed alongside information indicating what the chief medical officer or the Department of Health recommended as a low risk drinking level, that would be helpful.

On the information the industry gives and the way it has consistently attacked our research, it has been the practice for it or consultancies it has funded to attack it, or it subject to attacks from libertarians who are ideologically opposed to public health policies generally. They have tried to misrepresent our research by misrepresenting the methods used or the results to place it in a slightly different light. They often pick up on small elements and either misrepresent them or exaggerate their importance. Let me give a few examples. International evidence suggests heavier drinkers are slightly less responsive to price than other drinkers. They are just a little

less responsive, but we often find that the industry presents them as being unresponsive, which is wrong. It is simply not the case.

Mr. Colin Angus: To follow up on that point, a recent study found that they were potentially more responsive to price, but the difference was not statistically significant. However, the industry misrepresents this in stating they are not more responsive to price. That is what we have been saying all along; it will try to defame the evidence, irrespective of the findings.

Dr. John Holmes: Another example is that we have regularly updated our estimates of the impact of minimum pricing over time both in Scotland and England. Each time, because of inflation, an increasingly smaller proportion of the market is affected if we keep to the same minimum unit price. The industry has represented this as us correcting rather than updating our estimates. There is a sense that we are being undermined in a slightly underhand way. The reason it undermines it is it does not have any evidence to support its case that pricing policies are ineffective. All the international evidence agrees that increasing the price of alcohol reduces consumption and reduces harm. They have tried to undermine this because they do not have evidence to suggest anything different. When the committee hears evidence from the industry, I urge the members to press industry for the details of its evidence because that is where it begins to become clear that the industry's evidence is not quite what it appears.

Mr. Colin Angus: This was a point picked up in a recent House of Lords committee report in the United Kingdom, entitled A New EU Alcohol Strategy? There is a short paragraph in the report about the industry approaches which states that the researchers, whom that committee had in at the beginning, stated the industry is always sniping at their research. The short summary states the House of Lords committee, after it had spoken to the industry, sympathised with the academics because the industry was quick to pick holes in the research and try to knock it but was reluctant or unable to provide evidence to support its own perspective. it would merely knock the evidence of others without being able to support its own position with evidence.

There are a few other points. It might be helpful to give a few descriptive statistics about the population. According to the definitions Dr. Holmes described, 78% of the population drink at moderate levels. That is the vast majority. The 22% of the population who drink at increasing or high-risk levels are drinking 66% of all of the alcohol and spending 61% of the total spent on alcohol. The consumption or spending is concentrated predominately in this small group, and these consumers account for almost all alcohol related deaths and 87%, by our estimates, of alcohol related hospital admissions. Therefore, the problem is quite concentrated in a relatively small group who also happen to be those who buy the cheapest alcohol, which is why minimum pricing is a well-targeted measure.

On the distinction between those in poverty and those not in poverty, to return to the beginning of the questions, those in poverty are more likely to be abstainers. Some 30% of those living in poverty do not drink at all compared with 20% of the rest of the population. Those who drink alcohol at increasing risk levels drink less than their counterparts living above the poverty line. That switches around when one looks at the high-risk drinkers. High-risk drinkers in poverty drink more, and are buying a lot more of the very cheapest alcohol right at the bottom of Dr. Holmes' distribution. The proportion of the population which is drinking at these high-risk levels is similar among those in poverty and those not in poverty, at just over 5%. In terms of absolute numbers, they number 36,000 of those in poverty and 150,000 of those not in poverty. It is inaccurate to state that all the high-risk drinkers are in the lowest income groups. There are many people on higher incomes who are drinking at harmful levels. As Dr. Holmes stated, those living in poverty are buying the cheapest alcohol and suffering the highest rates of

harm. The rates of deaths and hospital admissions is approximately 40% higher among them than among those not living in poverty. These are the people one would want to target if one's aim is reducing harm.

On price distributions, I have some beautiful graphs in the report that I was proud of having produced which disaggregate prices into different types of drink. In doing that, I can no longer tell the committee exactly the median for all types of drink.

Senator John Crown: What is Mr. Angus's guesstimate? What is the median cost of the unit?

Mr. Colin Angus: In the on-trade, €2.30 is the median price paid and in the off-trade, it is approximately 75 cent, but these vary. The split, between the on and off-trade, is roughly 50:50. These are ballpark figures.

Dr. John Holmes: There were some questions about the timing of effects. Our model works only on a yearly basis. We estimate that when prices go up, we would see a change in consumption within a year. That is what the evidence internationally suggests. When prices change, one sees a quite short-run effect. I suspect it is not immediate, but I would anticipate that within weeks one would begin to see quite big changes in consumption because, ultimately, consumers make purchasing decisions based on the prices they see. There are some slightly more lagged cultural changes that happen as well as a result of a price.

The health effects are not immediate. That is because some of those who are drinking heavily today will not die from their drinking until ten or 20 years in the future. It takes time to develop liver cirrhosis and alcohol-related cancers. Similarly, there are also people alive today who, even if they stopped drinking today, will die of liver cirrhosis. They have already contracted it. It is not curable. They might die later if they stop drinking, but they will die of it. There is what we call a time lag and, after 20 years, we assume we will see the full health effects where all those effects are played out and we see the full impact. One will see quite a big chunk of the health effects immediately and the report provides some evidence on what we estimate one would see following the first year, but one would see the full effects emerge over the next 20 years.

Whether we would see in Ireland the 4.4% reduction in consumption that has been reported on average in the international literature is quite difficult to answer because it is an average across many countries at different times.

Deputy Peter Fitzpatrick: Are we any different from other countries?

Dr. John Holmes: Ireland is quite different, depending on which countries one is looking at. The United States is a number of different countries combined into one and there are quite different cultures. There is everything from Utah, which is totally dry, to California and New York, both of which are similar to Europe, to some of the southern states which have strong religious influences. It is quite different.

I would say that Ireland is likely to see an impact. It is likely to be substantial and to be of that order of magnitude, but I could not say it will be 2% or 7%. I would not like to put a specific number on that.

Deputy Peter Fitzpatrick: Dr. Holmes was commissioned to report on Ireland and Northern Ireland. Are we both compatible?

Dr. John Holmes: Largely, yes. In terms of alcohol, the main difference between Ireland and Northern Ireland is that the taxes are a bit higher in the Republic, particularly on certain products, especially wine and cider. Broadly, there are similar drinking cultures. The cost of living is also a bit higher in the Republic but broadly I would expect to see similar effects between the two countries. I would not expect the effects of minimum unit pricing to vary massively across the United Kingdom and Ireland.

Mr. Colin Angus: As well as the different tax rates, there are a few other reasons one might believe that the same level of minimum unit price might have a greater impact in Northern Ireland. Partly, that is to do with where they do their drinking. In the Republic, consumers do more of their drinking in the on-trade - in pubs and restaurants - where alcohol is more expensive anyway and will be almost entirely unaffected by a minimum price. In Northern Ireland, distribution is slightly different. Consumers do more of their drinking at home and more of their total alcohol consumption is potentially affected. They also have a slightly higher baseline rate of alcohol related health harm and they stand to gain slightly more for each incremental reduction in consumption, but the order of magnitude is similar.

Dr. John Holmes: I was asked what is happening in other places in Canada. Minimum pricing, or at least something close to what is being proposed in Ireland and in the United Kingdom, has not really been tried anywhere else in Canada. Russia and some of the other former Soviet states have had minimum prices, say on vodka or beer, but those countries are quite different because they have large illicit markets, high rates of alcohol consumption and significant problems of alcohol dependence of an order of magnitude greater than we see in western Europe. What has gone on in those countries, because the policies and context are different, cannot tell us much that is helpful.

The United Kingdom and Ireland are pioneers in terms of trying to implement this policy in a systematic way. That means we do not have a significant amount of evaluation evidence. We only have what has come from Canada. That is why our modelling has become so important.

What is important about our modelling is that it is not directly based on previous minimum price policies. It synthesises all the best evidence we have available on the relationship between prices and consumption and between consumption and harm. We bring that together, ask what we know and set out what we do not know. We also try and help policy-makers think about what those things we do not know might mean for the effects of a policy. The general conclusion has been that there are some uncertainties, there may be some unintended consequences but we remain pretty confident that harm reductions overall would ensue from a policy.

There were questions about what else works, and the point was raised about very high-risk drinkers or dependent drinkers. Minimum pricing is not a silver bullet. It is a public health policy. It is about the 20% to 30% of people who drink above recommended limits and thereby increase their risk of health problems. It is not about those very heavy dependent drinkers who have a much more narrowly defined problem. If one wants to tackle those people, there are alternative policies which can help. We are talking about treatment, in particular. A recommendation we would certainly make is adequate resourcing and alcohol treatment services. Treatment has been shown to be effective.

Many dependent drinkers buy large quantities of cheap alcohol, so they will be directly affected by minimum pricing. Therefore, we would expect to see some reduction in their consumption. It might not stop them being dependent drinkers, but it might reduce their drinking from 120 standards drinks per week, or far more in some cases, to 100 standard drinks per

week. That might not sound like a lot, but in terms of their risk of suffering health problems, it really makes a difference, particularly when one aggregates that across a few hundred thousand people drinking at that level.

Dependent drinkers do not emerge out of nowhere. They become dependent drinkers for many reasons. One of the things that facilitates their addiction is the availability of large quantities of cheap alcohol. We do not model this aspect and there is not a huge amount of evidence for same, but it is reasonable to expect that the removal of very cheap alcohol from a market will prevent some of tomorrow's dependent drinkers reaching very high consumption levels.

There were questions on how I might change the culture of drinking and whether people would return to pubs and restaurants. That is not something we model directly. Our work is quite data-driven. There is a lot of evidence on how much people drink but there is not a lot of evidence on where they are drinking their alcohol. Therefore, we have to make some inferences and map across from evidence on retail revenue for different sectors. I will explain what we expect to see. We know from various research that one of the reasons people drink less in pubs is because supermarkets and shop prices are much lower. That is a factor which helps people to drink at home instead. As prices go up, we would expect to see some people return to pubs and restaurants. Cultural issues have also driven this change. In the heyday of the pub we did not have the wine market we have now and wine is a product that people primarily consume at home. Society has also changed. People work longer hours, they generally go out more, they live less in communities, particularly middle-class people, and they commute more and live more in the city and urban centres. There are other reasons for the decline in the pub market than just prices. None the less, we would expect some impact, or at least we would hypothesise there could be some impact from minimum pricing.

I was asked about the impact on young people. I can say that people are affected by this policy to the extent that they buy the alcohol that is affected, or at least that is what we can be more confident about. Young people tend not to buy huge amounts of this cheap alcohol because they tend to drink more of the on-trade. The price in the pub will not be affected by the policy as it is already well above the minimum price threshold. That said, young people buy cheap alcohol and are price responsive because they tend to have lower incomes. Therefore, we would expect the policy to have some impact on them. When we looked at this aspect in the UK, although we did not look at the impact on young people directly in our Irish report, we did do so in our UK and Scottish reports and we have seen some impacts. They are greater than the impacts on moderate drinkers and smaller than the impacts on heavy drinkers, but none the less they exist.

Chairman: The committee has recently concluded a debate on plain packaging on tobacco. Would a warning label help? Would the placing of pictures on bottles warning about the negative effects of alcohol work rather than just text?

Dr. John Holmes: I believe it would help. As far as I am aware, explicit graphic warnings placed on alcohol products has not been done anywhere in the world. Warning messages have been done and the evidence suggests, particularly in America, that they heighten people's awareness and change their intentions.

Chairman: Are they warnings in text only?

Dr. John Holmes: Yes, I refer to text messages and not graphics. They change people's intentions but they do not necessarily affect behaviour. It comes down again to the point that in a very liberalised alcohol market with relatively little regulation on how alcohol is marketed,

the prices at which it can be sold and the level of overall availability in shops, simple messaging might not be enough on its own to change behaviour. Nonetheless, there are impacts, just not necessarily on behaviour.

There were questions on how to choose minimum price and increase it over time. In terms of choosing it, one must balance the impact on moderate drinkers against the impact of bigger health benefits. Clearly, the higher one goes with a minimum price, the bigger the health effects, although if one goes so high, it may result in a big restructuring of the alcohol market. The industry might fundamentally decide this is not the way to should sell certain products any more and make other products. In that case our estimates would start to become rather less robust.

One trades off in terms of the bigger health impact. It is obvious that the greater the level of alcohol consumed by low risk drinkers that is affected, the bigger the effects one will have on them. The question for the committee and the Government is how much impact they are willing to accept on low-risk drinkers to get the bigger health effects. That is not a question we can answer. We could make a recommendation but it would just be our personal view that is based on our personal values, so I am not sure that is especially helpful.

In terms of how one increases minimum pricing over time, the Scottish Government has faced this question as well but has not answered it, as far as I am aware. It said that it needed a mechanism and needed to think about what that mechanism would be, but it has not made a decision yet. Some obvious things to think about are inflation. We talk a lot in alcohol research about affordability, which is inflation adjusted to take account of household and personal incomes. The committee and Government may want to look at whether one can set a threshold that stays the same in order that a minimum price keeps cheap alcohol equally affordable over time. Within that, one might like to think about equally affordable for whom. One might find one is making it increasingly unaffordable because the metric is from the population and not from low-income people. If the metric is based on affordability generated by a population average and not from the low-income people, one might find that one changes affordability for certain groups more than others over time. There are some quite complex things to think about. We hope to start research on this issue in the near future.

Mr. Colin Angus: Inherent in all the results that we have presented in our report is that the minimum price would be inflated to remain the same in real terms across time. If the Government decided to set a minimum price but not introduce some kind of inflation mechanism, it is our belief that the expected effects would be less than those that we have provided.

Dr. John Holmes: There was a request from Senator van Turnhout for more evidence about illicit drugs.

Senator Jillian van Turnhout: Yes.

Dr. John Holmes: There is not a huge amount of evidence on how people substitute illicit drugs for alcohol.

Deputy Eamonn Maloney: What is the difference?

Dr. John Holmes: Does the Deputy mean between illicit drugs and alcohol?

Deputy Eamonn Maloney: Alcohol is a drug.

Senator Jillian van Turnhout: We are discussing illicits.

Dr. John Holmes: I would agree with that to a certain extent but I think an historian would have a much longer answer. The evidence that exists has been reviewed but it has been found to be quite inconsistent. Sometimes and with some drugs, people will substitute them for alcohol. Other people with other drugs will treat them as complements. That means that if they stop drinking, they will also stop taking the other drugs or they will reduce both.

Senator Jillian van Turnhout: Done through the pathway of alcohol.

Chairman: Have the witnesses considered changing the ingredients to reduce the strength of alcohol?

Dr. John Holmes: We have not done so. There has been some movement to do so in the UK by the UK alcohol industry as part of the public health responsibility deal with which the committee may be familiar. The industry promised to take 1 billion units out of the market by reducing the strength of some existing beverages. That has involved beers like Stella and Heineken being reduced from 5% alcohol by volume to 4.8%. It also involved introducing and promoting new low-strength beverages.

On the surface, that is probably a good thing. It is a good thing if we provide more options to consumers. It is a good thing if we provide people with the opportunity to drink lower strength drinks, if they want to. There is very little evidence that these policies are effective in reducing consumption because we do not know who is drinking those lower strength drinks. It might be that the moderate drinkers are now drinking the same amount they were before but are adding some lower strength drinks on days they would not otherwise have drunk. Similarly, abstainers may now be drinking some low-strength drinks. We do not know what is going on. The industry has made some claims that it has succeeded in this billion unit pledge. We dispute that and the committee will hear more about that in the coming weeks.

A nice example of substitution versus complements for illicit drugs is that young people's alcohol consumption is falling off a cliff in the UK. There are far more abstainers and far more young people drinking at lower levels than ever in recent years. This seems to be a very consistent and robust trend. The interesting point is that it is not being replaced by young people doing other things. They are not taking up smoking, or smoking more cannabis or taking more ecstasy. The data does not cover legal highs so we do not know what is happening there. The suggestion seems to be that when alcohol consumption is falling among young people, consumption of other substances is falling as well.

I forgot to make one point about the industry. Our research has been published in a wide variety of scientific journals, the world's leading medical journals, *British Medical Journal* and *The Lancet*. The World Health Organization, WHO, has also picked it up and recommended it, as have the National Institute for Health and Care Excellence, NICE, in the UK and a whole range of royal medical colleges in the UK and abroad, and their equivalents. By contrast there has not been a single publication in a peer-reviewed scientific journal which has criticised our work in any substantial way. There have been a couple of suggestions for how we might build on it but nothing has said this work is simply wrong. That is quite important. The publications the industry cites are soft publications, think tank reports, things they have submitted to committees such as this one. There is no credible scientific attack on our research that has not been funded by the alcohol industry.

Mr. Colin Angus: I would like to pick up on some issues around the edges such as numbers for the impact on household budgets for people on low incomes. For the low risk drinkers we estimate a reduction of €4.50 per year, almost no impact on their spending. For increasing risk drinkers it is €41 and for high risk it is a reduction of €60. They are small savings impacts. We do not estimate that the policy would lead to a reduction in the budget for other things for people in low income households because although the alcohol they buy is more expensive, they buy less of it and that cancels it out.

There was a question about people substituting down, in other words, if the market reshuffles itself do people start buying cheaper alcohol. In a sense that is incorporated in the price elasticities that we use to estimate all of this. That is incorporated into our estimates of impact on consumption. What it does not consider is if one believes that cheaper alcohol is fundamentally worse in some way than the same volume bought at a higher price. The evidence does not necessarily suggest that. The harmful component is the alcohol. The evidence even suggests that illicit alcohol is harmful only in the sense that it is strong and has lots of alcohol not because it has some other nasty chemicals that are also bad for one.

Younger people tend to drink more on average and it is true that they drink more in the pubs. The gradient across age is not that great. By our estimates, approximately 38% of their consumption is in the off trade whereas it is 46% or 47% for 35 to 54 year olds. There is not a huge difference. One might expect, although we do not have the figures here, that the impact of the policies on their consumption overall is quite similar. It is important to note that young people do not tend to suffer as much alcohol-related harm because they are young and not as ill. Young people do not tend to die as much as older people. That is a fact of life. If one is interested in the harm outcomes one will see that the policy has a much smaller impact on young people. That is because their baseline rate of harm is very low to start with.

Chairman: After publication of the heads of the Bill some comments on the price issue were similar to what Deputy Ó Caoláin said, and there was the question of whether this penalises low risk drinkers for the ills of others.

Dr. John Holmes: This is a difficult issue. The low risk drinkers are largely unaffected but they are affected to a small degree. Although costs for the harm caused by alcohol vary, they run into several billion euro in Ireland. The low risk drinkers are paying for that, through taxes and as victims of some of the problems such as alcohol-related crime and the general social disorder. Some victims of alcohol-related harm are some of the most vulnerable people in our society. The poor suffer worse consequences of their drinking than the better off. There are victims of alcohol-fuelled domestic violence, the broader victims of alcohol-related crime and the dependent drinkers whose drinking is facilitated and perpetuated by the availability of cheap alcohol. It is for the Government to balance the different priorities and reach a decision. There are solid arguments about why everyone in society should make a contribution to reducing the harm alcohol causes because that will benefit society as a whole and some of the most vulnerable people in society.

Senator John Crown: Having heard this compelling evidence, I believe some or all of the increase in revenue which is generated for someone by unit pricing should be taken into the public Exchequer and used for research. I also believe that we will have in Ireland a near unique opportunity to do original research but also to confirm the Canadian research if we do this. We should set about doing this prospectively and put structures in place to collect all of the relevant health and consumption data. If we are asked to renew this legislation at some stage we will be in a good position to show its real impacts.

On a very minor medical point, the reason some people think the same number of units of different forms of alcohol has different effects is that some of the other effects of alcohol that we are aware of, apart from the effect on the liver, cancer causation, etc., are due to some of the congeners in alcohol. For instance, one might have a worse hangover for the same number of units of alcohol in different kinds of drink depending on some of the other chemicals present. It does not mean less damage to the liver if one does not have a hangover from a "purer" or less adulterated alcoholic drink. That is not how it works.

Deputy Caoimhghín Ó Caoláin: After such a long examination of the detail of the witnesses' case, we have come full circle and Senator Crown has now reflected on something I argued for at the outset. I am not going to labour the point but it will be a missed opportunity to use the additional revenue for good and required purposes, particularly focused on the victims of alcohol abuse. That sadly will continue. We need to be mindful of that and I do not want to see the opportunity missed but it would appear from the draft legislation that course will not be taken.

Dr. John Holmes: To follow up on that, in Scotland a levy on the big supermarkets was proposed. Rather than treat it as a tax and take money from all retailers there would be a levy on the large ones which would claw back some of the additional money they got from alcohol sales. I am not sure what happened in that regard. Minimum unit pricing has not yet been introduced in Scotland. I am not sure whether that provision made it into the legislation. The committee might consider the introduction of a levy on specific retailers as an alternative to minimum pricing.

On the point about evaluation, obviously we agree that research is necessary. We discussed that issue with officials from the Department prior to the meeting. In Scotland, one of the limitations in terms of how it has been able to evaluate its alcohol strategy has been the lack of good quality baseline data. Data collection needs to be done prior to commencement of the parliamentary process. It is not acceptable to wait until the legislation has been passed to commence data collection. A lack of sufficient baseline data results in a weak evaluation. Data collection needs to commence early if a proper evaluation is to be made.

Mr. Colin Angus: In addition, by the time a measure has gone through the legislative process the industry is likely to have already started to respond. As per the Scottish pricing data, bottles of wine which were previously sold for just under the minimum price threshold have increased during the past three or four years to just above that threshold. It is unlikely that that is a coincidence. Some of the impact of the policy will be lost because the industry will already have started to react it.

Chairman: I thank Dr. Holmes and Mr. Angus for attending today's meeting and for their impressive presentations and engagement.

The joint committee went into private session at 1.12 p.m. and adjourned at 1.15 p.m. until Tuesday, 24 March 2015.