DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 6 Márta 2019

Wednesday, 6 March 2019

The Joint Committee met at 9 a.m.

MEMBERS PRESENT:

Deputy Stephen S. Donnelly,	Senator Colm Burke,
Deputy Bernard J. Durkan,	Senator Keith Swanick.
Deputy Alan Kelly,	
Deputy Kate O'Connell,	
Deputy Margaret Murphy O'Mahony,	
Deputy Louise O'Reilly,	

In attendance: Deputy John Brassil.

DEPUTY MICHAEL HARTY IN THE CHAIR.

Business of Joint Committee

Chairman: My apologies for starting the meeting late. I propose that the committee go into private session briefly to deal with some housekeeping matters.

The joint committee went into private session at 9.12 a.m. and resumed in public session at 10.25 a.m.

National Medicines Strategy: Discussion

Chairman: The purpose of the meeting is to begin consideration of a national drugs policy. The committee has invited representatives from Access to Medicines Ireland to give their views on how the policy may be drawn up. Access to Medicines Ireland is a membership group composed of medical professionals, activists and concerned members of the public. The group is committed to ensuring that medicines are made accessible at a fair price, and that medical research and innovation is directed at areas of greatest global health need. On behalf of the committee, I welcome Dr. Kieran Harkin, Dr. Ciara Conlon and Mr. Robbie Lawlor.

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

I advise the witnesses that any opening statements they have made available to the committee may be published on the committee's website after this meeting.

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

I invite Dr. Harkin to make his opening statement.

Dr. Kieran Harkin: We are grateful for the opportunity to address the topic of fair and equitable access to medicines. Members will be aware that health systems across the world are faced with the challenge of delivering safe and effective care within the context of limited budgets. This is certainly the case in Ireland, with our growing and ageing population. This challenge is compounded by spiralling medicine costs and the ever-increasing demand for access to new, high-tech and innovative medicines. It is clear that unless addressed, the current system of medicines development will continue to heap financial pressure on a strained health system and will put pressure on Governments to reimburse medicines at any cost. It will also continue to deny patients access to essential medicines.

Members will be familiar with examples of problems of access to orphan drugs such as Orkambi, Spinraza and Pembro, which are now almost household names. The greatest economic challenges arise, however, when high price tags are attached to drugs that are used to treat more common diseases. Hepatitis C treatment drugs were introduced to Ireland in 2014 with a list price of €80,000 for a 12-week course. At that time, an estimated 20,000 to 50,000 patients were in need of treatment, which carried an estimated budget impact of €4 billion. Fortunately the monopoly was broken and with the arrival of a number of similar drugs, the price was significantly lowered. I draw the committee's attention to our written statement in which we had mentioned a price of €46,000 per treatment course. I have since been informed that this figure was much higher and was, in fact, €80,000 in 2014.

The difficulties we currently face will appear minimal when new cancer treatments come onto the Irish market. CAR T-cell therapies, for example, will appear with a price tag of $475,000.

I must make it clear that while we are aware that much great work is being done to maximise efficiencies and to create opportunities within the current system, we believe that ultimately the drugs development model is in need of radical reform. The fundamental problem with the current model is that a patent holder is permitted to demand as high a price as the market will bear for the duration of the associated 20 year monopoly. We believe that inherently within the current system lies a power imbalance whereby the interests of the pharmaceutical industry take precedence over the interests of the public. This is a case of the tail wagging the proverbial dog.

Mr. Robbie Lawlor will continue this presentation.

Chairman: I thank Dr. Harkin.

Mr. Robbie Lawlor: While the pharmaceutical industry might claim that high prices are essential to encourage innovation, a recent report from the World Health Organization, WHO, concluded that concerns that lower cancer medicine prices might impair future research and development would seem to be misplaced. Evidence suggests first that prices of cancer medicines bear little or no relationship to research development costs. Second, financial returns on cancer medicines are high. Third, the potential impact on revenue due to lower prices could be offset by higher volume, especially when the marginal cost of production is low. Fourth, governments and the non-profit-making sector have made substantial contributions to the research and development of medicines through direct funding and other incentives.

There are other problems with the current research and development model. There is a lack of financial transparency to justify the high prices the industry places on drugs, with industry citing "commercial sensitivity". Research and development is directed towards projects which are likely to maximise shareholder profit as opposed to public health gain, hence a plethora of "me too" drugs of limited therapeutic advantage and an absence of research into new antibiotics to address the problem of antimicrobial resistance. There is silo-based research, with companies working on similar research projects but with no communication between them, which may lead to duplication of research and missed opportunities for shared learning. There is high expenditure on marketing and we know from research that double the amount is spent on marketing of drugs compared to what pharma puts into the research and development of new drugs. There are also high senior management salary costs. For example, the CEO of Biogen, the pharmaceutical company that makes Spinraza, received €12 million in pay, shares and other compensation in 2017, even though we cannot reimburse Spinraza due to the high cost of the drug. A huge proportion of investment in research and development, estimated at 30%,

is funded globally from public sources but without public return. In this respect, the public is paying twice for a drug, as seen with sofosbuvir, the hepatitis C cure, to which Mr. Harkin referred earlier.

Access to Medicines Ireland recognises the efforts of the Government to try to contend with the high cost of drugs. It has introduced reference pricing and generic substitution, negotiated deals at a national level with the IPHA and entered the BeNeLuxA pact at an EU level, all of which are welcome developments in the effort to ensure and improve access. This has delivered savings and promises to deliver more. In truth, though, these measures can only be considered as doing the best we can within a very broken system. The high cost of drugs is caused by a systematic problem and our policy efforts to date are constrained by that very system. Together with international organisations such as the UN, the World Health Organization and various campaign groups, we believe there are specific measures that can be taken at an Irish, European and global level. With regard to transparency, we should support the upcoming Italian resolution on transparency at the World Health Assembly. We should press for transparency at an EU level and we should attach conditions to public funding of research and development to require increased transparency for any drugs developed as a result. For price control, we should press for conditions to be attached to research and development grants, both at national and EU level, to ensure there is a price control down the line. We should consider the use of flexibilities in international patent law, such as compulsory licensing for certain drugs. In this case, we should potentially push for Spinraza in Ireland. In February, the UK Parliament discussed the possibility of a compulsory licensing in respect of Orkambi, which has put pressure on the manufacturer, Vertex, prior to forward negotiations this month. Within recent weeks, the Swiss Government has been petitioned to issue compulsory licensing for a Roche cancer drug, pertuzumab.

In the long term, the use of market exclusivity as an incentive to develop new medicines must be set aside as this disempowers governments seeking to determine a fair price. Alternative incentives for research and development should include upfront government funding in the form of grants and prizes. All medicines developed as a result would be patent-free and manufactured generically at affordable prices. Such models have led to successful research and development by public-private partnerships, such as DNDi - the Drugs for Neglected Diseases initiative. Ideally, an EU grouping or an global organisation such as the WHO research and development observatory needs to be established as suggested by the UN High Level Panel on Access to Medicines. I will now hand over to Dr. Conlan.

Dr. Ciara Conlan: We believe a better system is possible but will only be delivered by parliaments recognising the problem and working together to find a solution. Governments need to work collectively in order to successfully negotiate with global industry. At the conclusion of the Netherlands Presidency of the European Council in 2017, Health Ministers discussed and made recommendations around the problems associated with monopoly markets and the abuse of the orphan drugs system. The recently established BeNeLuxA and Valletta political groups are a good step on the way to increasing intergovernmental co-operation and this needs ongoing support and commitment. In Britain, Canada and the Netherlands, parliamentary health committees have worked to advance the case for an improved system. The Italian Government proposed a resolution to the World Health Assembly this year seeking to improve transparency of pricing, research and development and production costs, including public sources of funding.

We believe the current research and development model is unsustainable and has the potential to bankrupt healthcare systems and to create a small and powerful oligopoly of hugely

profitable drug companies, whose primary interest is on shareholder profits rather than public health. We would like to quote Professor Mariana Mazzucato in her editorial in the *British Medical Journal*, where she stated, "The first important step to reaching a better deal is for governments to realise that they have the power to actively shape and create markets, and not just remain on the sidelines fixing broken ones, especially in the area of health that is heavily subsidised by the public". This resonates with recommendation No. 10 of this committee's report on evaluating orphan drugs in February 2018, which states:

> The Committee recommends that the State and the HSE has some role in innovation, in collaboration with university structure. It is the Committee's view that unless the State has some involvement over the R&D element of the orphan drug and high tech phenomenon we will constantly be on the back foot with regard to funding. The Committee affirms the need for a sustainable, affordable and perhaps even novel model of funding.

We believe the Joint Committee on Health is uniquely placed to take a lead in this area of pursuing reform of the medicines R&D model. We would like to thank the committee for granting us this opportunity to share our perspective. We would also like to take this opportunity to invite members to our annual conference on 16 April, where key experts and stakeholders on access to medicines will come together to discuss the problems and potential solutions. For now, we are happy to take questions.

Chairman: To open the discussion, the drug bill in Ireland is in the region of €2.3 billion a year. This committee has looked at the cost of drugs and came to the conclusion there are substantial savings to be made in respect of that bill. Before I open questions to other members, will our guests explain the nature of the compulsory licensing process?

Dr. Ciara Conlan: This goes back to international trade law. The TRIPS agreement in 1994 standardised patent law across countries with the result that one had to give a minimum of 20 years of patent protection. Obviously, there is a need to implement some flexibilities where there is a great public health need and countries are free to define their own public health need. One of the flexibilities in international trade law is the mechanism called a compulsory license, where one can, without the permission of the patent holder, produce the medicine domestically for sale at generic prices, while paying a small royalty or some royalty to the patent holder to compensate.

Chairman: Where does that operate?

Dr. Ciara Conlan: Malaysia has taken a compulsory licence for sofosbuvir and it is producing and selling the medicine. More recently, this has been discussed in parliaments in Europe, most recently in the UK, where there is still no access under the NHS to Orkambi. This was raised in the UK Parliament as a means of securing access to the drug because the price was too high to afford in any other way.

Mr. Robbie Lawlor: Research shows that between 2011 and 2016 there were over 100 cases of compulsory licensing being issued globally. Some 81 of those have been approved and of the 19 that have not been, the majority have resulted in the reduction of the prices, whether through voluntary licensing or through negotiations between pharma and the countries involved.

Deputy Stephen S. Donnelly: I thank our guests for their time. It is a hugely important issue. The combination of some miraculous scientific breakthroughs with the eye-watering associated costs is going to pose some big questions for us as a society. We seem to be getting to the stage where, with enough money, one can cure or treat a phenomenally wide and growing

range of chronic diseases and conditions, so we are going to have to figure this stuff out.

At a national accounts level, are there projections for the likely costs into the future of drug budgets? We know that treatments are becoming more advanced and that there are some incredibly expensive ones. They do not have to be orphan drugs and may include new treatments which can turbo charge a person's blood, stick it back into them and let their immune system heal them. Are there projections for the kind of money that Ireland would need to be spending in five or ten years time, relative to what we are spending now, to provide to Irish citizens access to the emerging world of orphan drugs and breakthrough therapies?

Dr. Kieran Harkin: I am not aware that there are and I would imagine it is quite flexible. One of the problems of the future is the unknowns. The new CAR T-cell therapies for cancer, which the Deputy mentioned, are being designed initially to treat a limited number of conditions, particularly leukaemias and certain forms of lymphoma, but the expectation is that, as the research continues, the indications will expand and therapy will be able to treat more common conditions such as breast, colon or lung cancer. If the price tag of $475,000 is attached to all of those conditions, the sky is the limit as to how much money could effectively be spent on the drugs.

Deputy Stephen S. Donnelly: One of the areas that Access to Medicines Ireland seems to be examining is what strikes me as a governmental equivalent to what the Bill and Melinda Gates Foundation did. When it tried to encourage large pharma to develop medicines for developing countries, there was not an economic model and, therefore, the foundation offered a prize to which a firm could gain access, which tipped it over to being commercially viable to do the research in the first place. Is that one of the measures to which Ireland would contribute? Is the scale required for that sort of prize something that Ireland could do on its own, or would we need to do it at an EU level?

Dr. Kieran Harkin: We would do it at an EU level and even at a global level. There are two issues, one of which is the amount of money we would spend, although we would not be spending any more money than we currently do, given that more than €1 trillion is spent globally on drugs. While we currently spend it at the end of the process, our model would result in the money being spent earlier, leading to far more money and control over the investment.

The other issue is that we need to act in parallel with the industry, which is global. Unfortunately, the global political structures are not as strong as the global pharmaceutical structures and they would need to be developed. While it certainly needs to be done at an EU level, it also probably needs to be done at the level of the United Nations, the World Health Organization and the World Trade Organisation.

Deputy Stephen S. Donnelly: Is the EU taking any steps in that regard?

Dr. Kieran Harkin: Yes, with Horizon Europe it has explored alternative funding.

Dr. Ciara Conlan: There are other initiatives, such as the Coalition for Epidemic Preparedness Innovations, which develops vaccines and diagnostics for potential upcoming epidemics. The EU is working on a large, publicly funded research project with civil society and on its completion, the results will be made available and accessible to the public. It will not be immediately privatised to make it something we cannot afford, which is important. Europe is already spending a lot of money on research and development and we need assurances that we will have access to the results at the end of the process.

Deputy Stephen S. Donnelly: Are there any EU prize funds? There are many ways it can be done, one of which is that we just do it ourselves. We can publicly fund universities, research centres or whatever, or create economic incentives for the private sector to do the kind of work we want it to do rather than it just chasing profit all the time, or both. Does the EU offer any such incentives?

Dr. Kieran Harkin: I understand that it does but on a small scale.

Deputy Stephen S. Donnelly: On the other approach, namely, publicly funded research of drugs, perhaps all the drugs that are discussed at the committee are produced by private pharmaceutical firms. Are there examples of breakthrough or orphan drugs that have come from public research institutes in, say, the past five years?

Mr. Robbie Lawlor: Yes, almost all the funding for the hepatitis C cure, sofosbuvir, came from the National Institutes of Health and the US Department of Veterans Affairs. In effect, therefore, it came from taxpayers' money and public funding. A pharmaceutical company, Gilead, bought the company that made the drug, Pharmasset, as well as its patent. Gilead then set the price too high for many people to pay. Globally, 71 million people live with hepatitis C and from research, we know that with €40 billion in funding we would be able to eradicate hepatitis C from the world-----

Deputy Stephen S. Donnelly: My question was whether there are examples. We know about Spinraza and Orkambi and we can list other private drugs. Are there examples of drugs that have come through public institutions and are being deployed as such, that is, not drugs which have been nobbled by private interests?

Dr. Ciara Conlan: All FDA-approved drugs between 2010 and 2016, which is approximately 200 drugs, had some component of public funding. It is a huge problem and we like to speak about it because there is currently no transparency of how much of each individual drug was publicly funded. Biogen, which makes Spinraza-----

Deputy Stephen S. Donnelly: I am asking a different question. Have any of these drugs come from publicly owned institutions, such as universities or public research centres?

Dr. Kieran Harkin: Yes, there is the TB Alliance, while the Drugs for Neglected Diseases Initiative is a public private partnership supported partially by Irish Aid and the Bill and Melinda Gates Foundation. Public private partnerships, therefore, have been developed in areas of neglected diseases where there is not much public interest and where there will not much great return. The initiative has developed new tuberculosis drugs and an effective treatment for Chagas disease. There is also a new malaria-----

Deputy Stephen S. Donnelly: Dr. Harkin has referred to public private partnership but I am referring to public only. I am trying to understand whether it is just the reality that the private companies must carry out the work and we must put in legal and financial ways of securing the intellectual property, IP, or is there publicly-owned research infrastructure globally that can do it? Are we reliant on the private companies to perform the research and development, clinical trials and so on?

Dr. Kieran Harkin: No, most of the direct funding for the TB Alliance came from government sources, including Irish Aid and the United Kingdom's Department for International Development. Some industry expertise was used but the trials were conducted largely by Médecins Sans Frontières. The bulk of the work, therefore, was done with full public support

with some assistance from industry, although the industry was certainly not the major player. Industry groups advised and assisted rather than directing and taking ownership of the project.

Deputy Stephen S. Donnelly: The research and development was done by publicly employed scientists.

Dr. Kieran Harkin: Yes.

Deputy Stephen S. Donnelly: Is there a recommendation on what the IP protection of 20 years that should be reduced to?

Dr. Kieran Harkin: Our position is that patent and monopoly-inducing incentives are not appropriate and that it is not appropriate for any period of time for the owner of a life-saving drug to be allowed to charge whatever it wants. While it is clear that there needs to be some incentive, such an ability is not appropriate. We realise that the protection is useful as an incentive, particularly for orphan drugs, where there is an added ten years. Our position is that patents, monopoly and market exclusivity are not appropriate incentives for developing drugs.

Deputy Stephen S. Donnelly: It sounds as though we are largely reliant on the private sector to do the work.

Dr. Kieran Harkin: Yes, that is true.

Deputy Stephen S. Donnelly: I acknowledge that Dr. Harkin was able to refer to one public private partnership but it sounds as though the private sector will do the vast majority of the work in this regard. If the IP is removed, which would remove the ability of companies for a time-limited period to charge a healthy margin, is there another model, given that the companies will still need to follow the money? Is there another model whereby they can still make a profit? Otherwise they will just not do the work.

Dr. Kieran Harkin: Yes, the research should be funded directly by Governments. It is similar to tolling roads. One can either pay for the road to be built upfront, or one can have the road built and then charge tolls for 20 or 30 years. Our belief is that the upfront direction of Governments is the more appropriate and cost-efficient approach and it will provide the greatest public health benefit for the money.

Deputy Stephen S. Donnelly: Let us say, in the case of a global pharmaceutical company, that a decision is made at a governmental or EU level to target lung cancer. While I have not seen the figures for a while, ten years ago the research and development cost for a typical blockbuster drug was approximately $5 billion, although I imagine it has risen considerably. Is the proposal that EU funds would be created whereby Pfizer, GSK or whoever it is, would be handed $5 billion or $20 billion and asked to develop drugs for specified diseases?

Dr. Kieran Harkin: First, the problem is one of transparency. No one actually knows how much it costs to develop a new drug. The pharmaceutical industry would say $5 billion, which most people would say is at the top end, with the prices more likely to be between $1 or $2 billion. The public private partnerships that we mentioned develop very effective new drugs for $500 million.

Deputy Stephen S. Donnelly: Let us say that it is somewhere between $1 billion and $5 billion. Is the idea that we would block-grant the pharmaceutical companies?

Dr. Kieran Harkin: It would need to be done in a number of ways. It probably would be

a pull-push mechanism. One might decide on what was to be developed and what funds were available. There would have to be a decision on whether there would be a competition to put out to tender, whether it would all be done in one block or whether the research would have to be broken down, with institutions competing for certain forms of research. It might also be decided to reward people after the product was produced and if the product was seen to be affordable. There is not much point in developing a very effective product only to discover afterwards that it is so expensive that no one can afford it. There are various different models by which it can be done.

Deputy Stephen S. Donnelly: I thank the witnesses.

Deputy Louise O'Reilly: I thank the representatives for coming in and for their presentation. According to the opening statement, the current research and development model is unsuitable and has the potential to bankrupt to healthcare system while failing to advance public health. It is very hard to disagree with that. Our questions are to try and scope out the potential for moving away from where we are. I fully appreciate that nobody has any sympathy for politicians, and we probably do not deserve much, but we end up stuck in the middle. Most of us are not medical professionals, although some are, and we get stuck between the funding, the families and the pharmaceutical industry. That is not a very comfortable place for us to be. My experience is that the current system is entirely set up to encourage that. One finds oneself in a situation where one wants to do right by the families, while the pharmaceutical companies say they must make a profit or else they will leave. I do not know how they balance that with what they say about caring about everyone. Whatever solutions we may have, we can agree that the current system is not working. It is not delivering for families and it can put politicians in an unpleasant situation sometimes, not that people will have much sympathy for us.

On public money, has Access to Medicines Ireland an idea as to how much money the Irish Government spends in research and development on medicines? Does that funding come with any obligations? In my previous life, I represented people in the education sector. One would see these fantastic institutes being built, often with a recognisable brand name on the side or some other form of sponsorship but when we probed what exactly the world of medicine was getting back, as opposed to the company itself, the latter seemed to get a lot in terms of labour and so on. How much do they spend and is there a protocol regarding the return to the State as a result? Are there examples of good practice in respect of the public return on public investment? It appears that while we have the capacity to invest and to subside it, we do not have the capacity to prioritise it.

Dr. Kieran Harkin: A parliamentary question on Irish investment in research and development was tabled earlier this year. The reply was that more than €100 million was invested directly. There also were other expenses to the State such as tax reliefs and tax benefits that were more difficult to measure. Therefore, we do not have an estimate on how much it costs the State over and above the €100 million but the amounts certainly were significant.

Dr. Ciara Conlan: There is the 25% research and development tax credit, which could be construed as indirect public funding. As far as I know, we do not measure return on investment. All the research and development money seems to be measured based on the uptake from industry rather than the good that it can do in public health.

Deputy Louise O'Reilly: On good practice, can the witnesses point to anywhere that has got it right and from which we could copy?

Dr. Ciara Conlan: Some places are getting there. There is a big campaign among universities to be socially responsible in how they licence their products and the patents they take out. It is important for a company that was a beneficiary of public funding to commit to making it affordable and available and having some price control at the end.

Deputy Louise O'Reilly: We need to get to the point where, regardless of whatever it is we put in, we have some influence over the direction the research takes in the first instance and over the eventual cost.

The Drugs for Neglected Diseases Initiative has been mentioned. I understand it has yielded some decent results but does it have the potential to be scaled up?

Dr. Ciara Conlan: All the recommendations say that. It is going that way in Europe and everyone is talking about it, it is not only us. The UN had a higher level panel on access to medicines that recommended a global pooled research fund to which we would contribute and then have control over the products at the end. This is something we need to do to secure the medicines we need at the right price.

Deputy Louise O'Reilly: Is there anything the Government could do to ensure the clinical trial process is more transparent? Of all the clinical trial results that are produced here, do we know how many are publicly funded? Are they all publicly funded? Are they all published? I am conscious that there is an effective subsidy in place, in some instances, for these clinical trials. That does not necessarily extend to sharing all the information.

Is there anything we can do by way of recommendation, either as a committee or as legislators, that would improve transparency, particularly with regard to clinical trials? I would like to get a handle on how many are done here, how many of these are publicly funded and what happens to the results.

Dr. Kieran Harkin: I am not sure if that was a recommendation or a question.

Deputy Louise O'Reilly: Is there anything we can do to improve on it?

Dr. Kieran Harkin: Traditionally, there is a real problem with research that is conducted by industry or others, in that research which produces favourable results is published and research which does not produce favourable results tends not to be published. There is a skewing of evidence and people look at it and think it is really good, forgetting that there is lots of unpublished information. There is now EU legislation, although I do not know if it has crossed the line yet, which insists that any clinical trials that have been initiated and conducted must have their results published within 12 months of completion, regardless of the outcome. Some of the medical journals will no longer report on clinical trials unless they have been registered before the trial took place.

Deputy Louise O'Reilly: Therefore the industry is effectively policing itself in this regard?

Dr. Kieran Harkin: The problem is that while some legislation has been passed at EU level, it is more observed in the breach. I read something during the week to the effect that approximately 40% of trials conducted in the UK are published, whereas 60% are not, so it is still very much a problem. I do not have figures for Ireland but it should be relatively easy to get them for studies that have been registered and then reported on.

Deputy Louise O'Reilly: I do not know how true it is but we have all read that most global

pharmaceutical companies will spend more on advertising than on research and development. If that is the case, it undermines much of the discourse on the subject. These debates get very heated because we are talking about seriously ill people and, in some instances, seriously ill children. The retort from the pharmaceutical companies is that they must make back what they spend on research and development. If it is true, and I suspect it is, that they spend more on advertising than on research and development, then their claim is undermined. I do not know if the witnesses are aware of whether that is true but it is something I have heard.

Dr. Ciara Conlan: Yes. We have heard references to that. In 2010, Knowledge Ecology International did a study that showed pharmaceutical companies spent 7% of what they earned from global sales on research and development. I do not know where the remaining 93% went.

Deputy Louise O'Reilly: Do the witnesses imagine that it goes on advertising?

Dr. Ciara Conlan: Not all of it is spent on advertising.

Deputy Louise O'Reilly: Is a good chunk of the money spent on advertising?

Dr. Ciara Conlan: Yes.

Dr. Kieran Harkin: It is true that the amount is almost twice as much. Ironically, the less useful a drug is, the more money companies must spend on marketing. A good drug will sell itself without the need to expensively court doctors, in particular, to persuade them to prescribe the drugs.

Mr. Robbie Lawlor: Marketing is not the only issue. We know that pharmaceutical companies spend vast amounts of money on share buybacks. A report entitled The People's Prescription shows that in the past ten years, Pfizer spent $139 billion on share buybacks and dividends compared with $82 billion on research and development, and that is not including marketing.

Deputy Louise O'Reilly: I thank the witnesses.

Deputy Bernard J. Durkan: I thank our guests for coming before us this morning and giving us the benefit of their advice. I agree with the views expressed that what is happening at present, whereby seriously ill people who know a particular drug is available and has beneficial effects are deprived of it unless they pay a ransom for the drug, is totally unworkable and morally wrong. The pharmaceutical sector must be regulated in some fashion and the best place to do so is at a European level. As I have said many times in the past, I do not think any one country can deal with this matter themselves.

I appreciate the tremendous work done by the pharmaceutical sector. It does very important and beneficial work in research and development as otherwise, we would not have the drugs at all. That said, there comes a time when the patient should not become the victim. Patients are being told that if they have enough money, they can have a drug now or it will be tested on them first as part of a trial but when it proves to be effective. the price will be increased. This is morally wrong and cannot be allowed to continue.

We, at this committee, have discussed the system many times. I believe that some means must be found at European level and it is not going to work at a national level because no one country, not even the more powerful ones, are prepared to do so. At present there are drugs that are not reimbursed in the UK, for example, because they are too expensive but they are effective. It is so sad to see patients being held to ransom when effective remedies are readily

available and at the same time, governments are being told to pay up or they will not get the drugs. I do not know how we can resolve the matter but we must do so through the European Union. We must use the power of the numbers in the European Single Market to impress upon the pharmaceutical sector that fair is fair. We must tell it that while we are prepared to go a certain distance, that we know the sector has invested and are taking into account the cost of the investment in research and development, they must be fair to patients. We must tell the sector we now think it is time that it ensures, having developed its facilities, that patients at least get an even break and we do not have the stark and sad situation whereby only the very wealthy can afford to live. I am not asking for a response to what I have said as I have said all of this many times before. We must go back to our colleagues in the European Union in an effort to encourage them to deal with what is happening, and deal with it throughout the European Union, from which we will all benefit.

Dr. Ciara Conlan: We need to show a good example for the benefit of our colleagues in Europe and shine a light on what is happening in Ireland and at EU level. Other Government health committees have compiled reports and made policy commitments in this area. I think we can make commitments at a domestic level. We are very keen that Ireland, at an EU level, would support the Italian resolution on transparency at the World Health Organization. We can also take domestic measures to build transparency around how pharmaceutical prices are reached.

Dr. Kieran Harkin: I thank Deputy Durkan for his contribution and I agree with everything that he said. He is right that it is more difficult to see what to do at a national level. Recently the Dutch commissioned a report to assess what they could do at a local level and came up with a number of interesting things. One is that they discovered they were funding research but just at the point when it might become commercially available, it was being handed up and the industry was taking it for a song. They discovered that if they invested just a little more and went one step further in the research to package it to be more commercially viable, then they would get much more value for money. They recommended in their report that a clause be inserted to ensure there is subsequent public input into price control down the line on research using government funding. This committee might usefully explore some options that we could use at a national level to reform the system.

Deputy Bernard J. Durkan: Yes, we are limited in what we can do at a national level. We have tried it before. Once upon a time I was a member of a health board where we tried it as well and it was not very successful. Let me outline the problem. There are 500 million people in the European Union and they are the answer. They are a powerful market that has a huge influence. Their pocket books are important as they can influence policy across the board in a way that nobody else can. Five million people may have a say in these issues but 500 million people would have a bigger say and we must be realistic. As I have many times before, we are members of the European Union but we do not always get the full benefits that we are entitled to from our membership of the European Union in terms of access to medicines, which has been deemed to be a fringe issue and is not seen to be a core issue for every citizen in the Union. The fact of the matter is that it is a core issue. It is an issue that can totally affect the lives of many families throughout the country and every day totally unrealistic prices are being sought for treatments at the present time. It is morally wrong that we should be in that situation and at the same time be part of the European Union.

I reiterate that we need to check with our European colleagues as to what the prices are in all of the member states. There is no good saying that we should select a number of states, as

we did in the past, say 12 or 13 states, and use the average price as a benchmark. That is not acceptable either. People have the same values and entitlements all over Europe and we need to assert ourselves on that one.

Deputy John Brassil: I thank the witnesses for coming here. From what I can gather, Access to Medicines Ireland is a group of concerned medical professionals who are trying to do something about the spiralling cost of drugs with a focus on the companies that produce the drugs and their associated research and development. Do the witnesses know the cost, or is it available, of developing a drug all the way from a molecule to a product that is available on the shelf? Is there an ability to work back from that and see what Governments could do? I might be speaking for myself. Perhaps I understand that what the witnesses would like to see is that governments would invest in research and development and, when a breakthrough is made, the company in question would charge €50,000 per treatment instead of €500,000 and the payback is that the investment is made up-front. The witnesses can correct me if I am misunderstanding what they are trying to do. We all want to achieve something. Last week, people with spinal muscular atrophy who are trying to get Spinraza over the line appeared before us. The BeNeLuxA model, which is welcomed by the witnesses, is mentioned. To my knowledge, Spinraza is available in the other three countries but not here. How do we explain that one away? We will start with that issue.

Dr. Kieran Harkin: The UN high-level panel addressed the issue of how much it cost to produce a drug. There are a number of sources. Part of the problem is the lack of transparency. The industry is intentionally refusing to publish the detail, which it says is because of commercial sensitivity. Having said that, there are a range of estimates from $150,000, which involved one of the smaller drugs. It depends on the kind of drug one is trying to produce. The latest figure was reportedly $4 billion, which was quoted by Forbes. This was a figure produced by the industry itself. Few people outside the industry would agree with the figure of $4 billion but would say it is closer to about $2 billion. The estimate is that in or around $2 billion will fund a pretty good drug.

Dr. Ciara Conlan: I would like to address the BeNeLuxA initiative. Deputy Brassil is right. Belgium and the Netherlands have negotiated a deal for Spinraza but Ireland does not yet have it. That is something that is very important that we can do at national level. If we are to be part of BeNeLuxA, we need to avoid tokenism. The strength of the BeNeLuxA collaboration will depend on each country's commitment to it. If one country decides that it can get a better deal and goes it alone, it will undermine the whole agreement, which is exactly the industry wants. It all goes back to transparency. We still do not know how much Belgium and the Netherlands are paying for the drug. This information is confidential, which puts us on the back foot when we are trying to negotiate as a country. We are a small market and the company is aware of that. It already has $1.7 billion in global sales. We must commit and be accountable for our participation in BeNeLuxA.

Deputy John Brassil: The witnesses mentioned Biogen. I am not sure what the remuneration of its CEO is. Companies will argue that they have a public health interest. They must have it to-----

Dr. Ciara Conlan: We have a small market in Ireland. The companies would rather lose that market - they are already making enough in sales - than offer the drug to this country at a price that is affordable, so they are putting their own profits above the lives of patients in Ireland with spinal muscular atrophy.

Deputy John Brassil: They would tell us that the price available in Ireland is equivalent to their deal with Belgium and the Netherlands, so who do we believe? Transparency might be the key to all of this. If we could unlock transparency, we might make progress. As somebody with a limited amount of knowledge in the industry, will a scenario ever arise whereby world governments will unite on a multilateral basis and say they will invest a specific percentage of their health budgets in research and development, give it to the various companies to invest and have a payback model when the drug comes to fruition? Is that something that is achievable?

Dr. Kieran Harkin: It is achievable and we are already seeing it in the area of antimicrobial resistance. This area does not have much commercial attractiveness for drug companies because if a company develops a new antibiotic, it must use it sparingly and be very selective regarding where it is used. The last thing a company wants is sales representatives knocking on every GP's surgery door advising them what to use and for what. Once a company develops the drug, it must hold it close to its chest so nobody is interested in it. I do not think any new antibiotics have been developed in the past 15 years, although I may be corrected. Many drug companies have simply declared that they are not even researching new antibiotics, so this is an area that is open. The WHO and the UN have an intergovernmental forum looking at how to develop new antibiotics and, when they are developed, how to distribute them. Clearly, there is no conflict because there is no conflict of interest between the interests of pharmaceutical companies and public health.

Pharmaceutical companies' responsibility is to their shareholders. They do not have a remit when it comes to public health. Any CEO who goes out of his or her way to jeopardise profit in the service of public health will be fired fairly soon. Obviously, to be effective as companies, companies need to be seen to have products that are useful and contribute to public health, but companies' remit is not public health. Their remit is making money. I am sure all of us around the table know that this is the case. This ties into the fact that when companies set the price of a drug, the price bears no relationship to how much it costs to bring it to market. Even if we did know how much it cost to bring a drug to market, companies would still say that they are going to charge €100,000, €200,000 or €300,000. It is like playing poker. It is a case of thinking someone has money or that someone is desperate enough and will pay. That is how price is determined at the moment. As long as we have a model that allows the manufacturer of a drug to charge what it likes, we will pay more than we can afford. By definition, we will be squeezed as much as we can bear.

Deputy John Brassil: The presentation suggested that public funds are used in pharmaceutical research. Will Dr. Harkin explain that so I understand where and how that happens?

Dr. Kieran Harkin: It involves much of the early research done in universities, which is funded publicly. A number of reports have documented that 30% of research and development overall is funded globally. The figure from the public purse that went into research was put down at $240 billion in 2015.

Deputy John Brassil: Dr. Harkin's contention is that when that research results in a drug being developed, the research element of it is not reimbursed or is not reimbursed in the same proportion that it should be.

Dr. Kieran Harkin: Absolutely. It is not reimbursed nor has the person who put in the money up-front got any input into price or transparency. If one asks how much the drug cost or where the funding came from, one is told it is not his or her concern. The funder has no rights once the product is passed on.

Deputy John Brassil: Are drug companies giving universities money towards research and do the universities then feel beholden to the companies? Is that happening?

Dr. Kieran Harkin: Yes, it is a symbiotic relationship.

Deputy Kate O'Connell: I thank the witnesses for coming before the committee, for giving of their time and for all they do, particularly Mr. Lawlor. It is very important that patients are out there advocating for others.

To follow on from the comments of my colleague, Deputy Durkan, on the EU, I have to agree that the solution here is the EU market and its 500 million people. We are being played off against each other when it comes to drug pricing. Deputy Brassil mentioned Spinraza, which I believe has gone through the BeNeLuxA agreement. We are given a price and then told it is not the real price, because the list price and the actual price are different. We are told information is commercially sensitive, etc. Transparency is clearly a big issue here. We seem to spend so much time dancing around and protecting pharmaceutical companies' confidentiality when people are suffering daily due to lack of access to drugs, as I am sure the medics are aware.

I am very supportive of centralising assessment through the EU. We are a body of people with essentially the same rules, so I cannot understand why each country is running this through its national equivalent of the National Centre for Pharmacoeconomics. That is the way we have to move.

When a company proposes a drug, it already knows its market. It already knows how many people have human immunodeficiency virus, HIV, hepatitis, or a rare condition such as cystic fibrosis. I am a pharmacist, but I think we should be very conscious that the responsibility of pharmaceutical companies is to their shareholders and not to public health. As legislators, that is where our concern arises. Over the last few years in this committee, I have seen that drugs can be available to those who get a good PR company, tell a good story and promote the right victims. We end up in a situation which I am sure is very concerning to our witnesses as medics, where those who shout the loudest often get the most. It is a huge injustice. Suppose that two children have debilitating physical illnesses. A drug comes out to treat one disease but not the other. By the power of the pharmaceutical industry, the child for whom the drug has been developed might get €500,000 a year in drug treatment. The child for whom no drug has been developed gets nothing. That is a huge inequality, and as a medical professional and a legislator, I find it very difficult. That injustice is probably why our witnesses are here today.

In regard to how we move forward on this, a lot of people speak about ring-fencing budgets. The witnesses can tell me if I am wrong, but I always find that if funding is ring-fenced it is a target rather than a bill. Let us suppose that an arbitrary figure of €100 is to be given to biosimilars or to orphan drugs. We always end up at €11. I am concerned about ring-fencing, because if the money is gone in March companies will ramp up their production of drugs to come onto the market in January. The drug released in June will never see the light of day and the patients will suffer. I am concerned about the ring-fencing model.

The opening statement referenced generic substitution and reference pricing. I have lived through that phase as a pharmacist. Biosimilars promise similar opportunities to those promised by generic drugs 15 years ago. I understand that legislation was brought in to allow pharmacists to generically substitute. There is huge pushback against biosimilar substitution from the usual suspects. Perhaps one of the doctors could give their opinion on this, or any data that might be

available. Are there any costings of the savings we would make if we substituted the top ten rare disease drugs or high-tech drugs with biosimilars? Every time we provide a branded high-tech product while a biosimilar sits on the shelf, somebody is not getting a treatment as a result.

I am aware that these are used all the time in the Netherlands. I met with a pharmacist in the Netherlands the other night. We seem to be behind the curve here. Is there a reason for this delay? Is it cynical to think that the position of big pharma in Ireland might have something to do with our slow progress in this regard?

Returning to the issue of the market, there is definitely a move in the pharmaceutical industry to pick the illnesses affecting a massive population, such as cholesterol, and not the very rare conditions. Firms pick a proper market. They do the sums and note there are, say, 3,000 children or adults with a certain condition. They multiply the numbers, determine their top price and cut off 40% to find the lowest point they can go to. To some extent this is all a game, but the game is costing lives and leaving people without medication. It is high time we stood up to these companies. They want to sell drugs and we want to buy drugs, but we are in a position where we have limited and finite resources.

I am quite interested in the issue of access to medication in the developing world where it affects vaccination, HIV control and hepatitis C eradication. I recently saw data saying that in Ireland and Europe, when we are exposed to fake news or incorrect information on vaccination, many people are able to look at the information, realise it is not as it seems and make their own informed decision. This reflects our belief in our public health system. I have seen evidence that in developing countries people may use the Internet as their only source of medical information. They may not have the benefit of an education system that develops critical thought and a public health system in which patients believe the GP and meet the hospital doctor. They may not hear about things on the news. Someone whose only source of news with regard to vaccinations, hepatitis C or HIV is social media can be a really good target for people trying to affect global vaccination rates, whatever their reason for doing so. If the witnesses have any information on that sort of bias, the challenges it poses to the developing world and how we protect those people I would be interested to hear it. Funding public vaccination programmes is absolutely pointless if herd immunity is not reached. It is a complete waste of time.

Dr. Harkin's comments on antibiotic resistance were very interesting. I had never even considered it before. There is no money in antibiotics. There is no money in developing a drug that doctors do not want or whose usage they want to restrict. I would be interested to hear any more information Dr. Harkin may have on that. Perhaps he could send it to me after the committee meeting. I am quite concerned about this. We can have all the vaccinations and HIV eradication programmes in the world, but if a super-resistant bug appears that is the end of us all anyway. There is no point in the rest. Perhaps Dr. Harkin could elaborate on that.

I read one of the documents on antibiotic resistance. There is now a movement called One Health that combines a view of antibiotic use's effects on the human population, the animal population and the environment. If I take an antibiotic and excrete a certain amount of it, it enters the water supply. Farmers put antibiotic bulk powder into pig and chicken feed. That is totally unrestricted. The Government does not charge any value added tax, VAT, on it either, but that is another day's work. Overuse of antibiotics in the animal world and the veterinary field combined with restrictions in the human world affect the environment, which is what we are all talking about right now. If Dr. Harkin has any research on that or a view he would like to share, I think it would be of value.

Dr. Kieran Harkin: To address the first two points the Deputy raised, we have done a lot of research into the cost-effectiveness of certain drugs. There has been much less research into the cost-effectiveness of other interventions. What is the cost-effectiveness of home help, physiotherapy or speech therapy? That is particularly the case in the context of a limited health budget, when a new drug appears, €2 million or €3 million is whipped out and other aspects are put aside. We need to broaden our concept and stop thinking about just how much the drugs cost. We should, instead, consider how much interventions cost. Is it worth is? I am sure there are other areas, such as MRI scans, where we are also overspending. We need a broader examination of the cost effectiveness of all health interventions. If it was realised that the cost of another health intervention could be more useful, it might make us think twice before spending large amounts of money on a particular drug of limited efficiency. I read in *The Sunday Business Post* last week about doctors prescribing a relatively low rate of generic drugs.

Deputy Kate O'Connell: For bio-similars.

Dr. Kieran Harkin: Yes. There is an over-reliance on the brand leader and limited clinical evidence for that. That should change and I see Dr. Barry from the NCPE has said he will go about doing that.

Dr. Ciara Conlan: Dr. Barry has spoken about proposing legislation which would mandate, unless there was good reason, the prescription of the bio-similar. He has spoken publicly about our bio-similar use of adalimumab being 2% of market volume whereas it is 80% in Sweden. That is definitely one aspect of the problem with our drugs budget. It does not all have to do with the presence of pharmaceutical industry. Clinicians and patients also need to be educated about the safety of the bio-similar drug and that it will be equivalent to what is currently being used. The fear aspect needs to be taken away. Dr. Barry has great expertise in this area and he will probably speak to that issue. I agree with everything that has been said, particularly about ring-fencing budgets for orphan and rare drugs. In the short term, it is a way to get things onto the market quickly. It will not, however, provide any incentives for the industry to lower prices and they may even rise, in that setting.

Mr. Robbie Lawlor: I thank Deputy O'Connell for her strong words. I am delighted she raised the issue of the developing world and lower and middle-income countries. We have spoken a good deal about Ireland and our issues, but we also have to recognise these policies can have far-reaching effects. I will speak about HIV because I work in that area. We know, thankfully, that because of generic drugs, the uptake of HIV medication has increased in use from around 9% or 10% of the affected world population, when the price was $10,000, to 53% of the affected population today. That is brilliant and is thanks to generic drugs. Some 47% of the population still do not have access to HIV treatment. We know such treatment stops AIDS-related deaths and the transmission of HIV. We are not there yet and one of the main reasons is the high cost of drugs.

Equally, I am on my fifth option for HIV medication. In Uganda, there is only access to two options. I would be dead if I had been born in a lower or middle-income country where there is only access to two drugs. The real question is why we put more value on my life rather than on the lives of all of my friends in Uganda. That is the current system. I am delighted Deputy O'Connell brought up the issue of the developing and lower and middle-income world. There can be far-reaching effects in respect of generic drugs and we need to understand that. Regarding education, there was initially a slow uptake of antiretroviral therapy. Many people at the time were uneducated and thought they could be healed by the power of God or that HIV was actually invented by the CIA in America. There were many conspiracy theories and they can

become rife in countries with a lower standard of education.

Thanks, however, to Irish Aid, which pumped a great deal of money into community representation and education programs, we have seen increased uptake of antiretrovirals. This model works and it needs to be used for vaccinations. In addition, there is also the issue of not reducing the cost of vaccinations by $5. Médecins Sans Frontières has done many reports on this topic. A small reduction in the cost can lead to a great increase in the uptake of vaccinations by the vast majority of people who want them. My perspective is that we should think of Ireland and what we can do at EU-level but let us not forget those whose voices are not being heard on the global stage.

Chairman: I will go to our second round of speakers soon. From what I can gather from the contributions so far, the tension is between the pharmaceutical industry, a commercial entity driven by profit and responsible to shareholders, and health services with limited budgets, responsible to the populations and patients they serve. That is where the negotiations start. The EU Council has stated it is within the competency of each member state to decide what drugs are approved and what price is paid. Are we being exploited by pharmaceutical companies playing one country off against another? We have seen representations made in the Dáil from groups stating that a certain drug is available in ten or 20 other European countries and asking why it is not available in Ireland. Moral pressure is being applied to Governments and politicians. We are all also subject to lobbying from big pharma companies concerning making orphan drugs available for rare and ultra-rare diseases.

We have presentations on that issue in the AV room here. The most recent was on Spinraza but there have been others for many other drugs. Moral pressure, therefore, is applied to Government and politicians but the same moral pressure does not seem to be applied to the pharmaceutical industry. It should clearly also have a moral and ethical responsibility if it has produced an effective drug. To withhold such a drug on the basis of exorbitant cost does entail a moral and ethical responsibility. The spotlight, however, is not shone on the company. Many representative groups do not go to the headquarters of pharmaceutical companies and make a presentation there. They come here instead and put moral pressure on the Government and politicians to pay. There should be a rebalancing of those responsibilities. The witnesses might comment on that.

I know the IPHA would contend it regularly negotiates prices with the Government. There was an expectation that the resultant cost reduction, I think it was in 2016, would be redeployed to the approval of new drugs as they came on the market. The IPHA would also contend that Ireland is way below the European average in approving new drugs. Of 153 drugs referred to by the IPHA, Ireland has approved 49. That may have increased in the past few months. There is an expectation from the pharmaceutical industry that savings generated from using generic drugs or negotiating cost price reductions should be ploughed back into new drugs. The IPHA would contend that is not happening. The witnesses might also comment on that.

There are, therefore, two issues. One concerns existing drugs and how costs can be reduced. We are all familiar with people who go to Spain or Portugal and buy certain drugs across the counter for a fraction of the cost here. There is obviously variation in cost. Why is Ireland not using its power as a member of European Union to get other European states to negotiate a common price? Why should a drug in Spain cost a fraction of what it costs here? Finally, there is also the issue of the new orphan and cancer drugs, drugs for hepatitis C for example, that come on the market all of the time. How can a small country like Ireland negotiate a price with a global pharmaceutical company? Surely, as Deputy Durkan said, we should be using our power

within Europe to secure a common price for all countries. I ask the witnesses to comment on all of those points.

Mr. Robbie Lawlor: I would like to comment on the first point. I work with many patient organisation groups to put the moral spotlight on the pharmaceutical industry. We have a real problem, not only in Ireland but globally, of patient groups being pitted against each other. It may be that a case is made for not paying for prophylaxis for HIV patients because that will lead to the withdrawal of cancer drugs from babies. That is what we see represented in the media. We are pitted against each other, although we are all just trying to get the best healthcare for ourselves. We all have that moral and human right. Anger may also be directed towards politicians, as we know, and against the NCPE process.

A major part of our work as a civil society organisation is to communicate with the public to redirect that anger to something productive. That is not to ask why is the HSE not paying for these highly overpriced drugs but to ask the fundamental question as to why we allow the drugs to be so expensive in the first place. If we can get society to ask that fundamental question, we can redirect our effort elsewhere. All stakeholders in the drug pricing paradigm need to come together to change that fundamental question.

Dr. Kieran Harkin: It is not our area of expertise but the agreement the State had with the pharmaceutical industry was that savings from generics would be for prescribing drugs. My understanding, however, is that all of that budget has been used up and, therefore, that almost all the savings due for new drugs have been used by the end of February. In previous years, when it was decided to approve and reimburse Orkambi, that took up a substantial sum of the moneys that had been pencilled in to be used for new drugs.

Dr. Ciara Conlan: We do not have that much clarity on whether the savings from 2016 have happened. I certainly have not seen evidence that those savings have happened, in the way of a budget analysis of how much they were and where they are being used now. I refer to a recent article for *The Irish Times* by Dominic Coyle where he mentioned that there was no clarity on that.

Chairman: I presume countries would defend their right to decide what drugs are available and what price they pay but there must be a benefit in a common negotiating policy where one country is not played against another but that seems to be what is happening. Each country has a different price for the same drug, so it depends on what the market will bear.

Dr. Kieran Harkin: Absolutely.

Chairman: Is there any movement in Europe that considers it from that moral perspective and decides that we should now have a united and common negotiating strategy, rather than each country adopting its own negotiating strategy, which seems to be a weakness?

Dr. Kieran Harkin: It was envisaged that Beneluxa and Valletta, an organisation of southern European countries, would perform that function and it has been disappointing that they have not done that. In Beneluxa, one country decided to approve Spinraza and the other not. It is still fairly early days, it is a difficult process and the hope still rests with the development of groups such as Beneluxa and Valletta.

Deputy Louise O'Reilly: It is interesting that Dr. Harkin would hold out the hope for Beneluxa because it is important that it would deliver. Outside our roles as Deputies or Senators, is there anything practical that we as a committee can do in response to the issues he raised? We

may not all agree on everything and there are people here who have a much more benign view of pharmaceutical companies than I do but we are all agreed that the system is not working, that it is not delivering for patients and that a system where the sick person who makes the most noise is the one who gets the treatment is not a good system. None of us can stand over that. We could pin all our hopes on a Damascene conversion for the big pharmaceutical companies in respect of morality or we could consider what practical steps we as a committee could take to address the issues. If the witnesses have a suggestion for something that the committee could do to address some of the issues raised, notwithstanding the variance of views, we are all united on the fact that the system is not fit for purpose, is not working and is not delivering for patients.

Dr. Kieran Harkin: It would be useful if the committee could explore further how much money the Government does in fact invest in public research and to see if there are any public health gains attached to such investment, or if there is any potential for public health gains to be attached to such investment.

Deputy Louise O'Reilly: Or if we could attach a proviso that further public investment is on the basis of a return for public health. That should not be a wild or strange concept but perhaps it is. We should consider that.

Dr. Kieran Harkin: Specifically we ask that it would have conditions of transparency, that we would be entitled to ask how public funds are being spent and that there be some price control on any subsequently successful drugs such that we would have some advantage when it comes to paying for products.

Deputy Louise O'Reilly: It is hard to define exactly what the investment is because if the laboratory has been built and staffed and a company sponsors a bursary of €30,000 or €40,000 that investment is on paper but the State has invested in the bricks and mortar, the personnel, the person who comes to clean the place, and the lights. It is difficult to do but it is not impossible and it is not impossible that future investment should be linked to some sort of return and public health gain. That is not an outrageous to ask for. Does Dr. Harkin think that is outrageous?

Dr. Ciara Conlan: The committee is probably going to interview other stakeholders in the coming weeks and it would be great if it could commission a report and bring together all that evidence. We would be happy to come back at the end if the committee had any further questions for us. The root causes of the problem we have are something to explore, taking examples from other countries which have done similar work such as the Netherlands, the UK and Canada.

Dr. Kieran Harkin: Several committee members were interested in what had been done in other countries. It might be interesting to invite some academics and politicians, particularly the Dutch Minister for Health and Ellen 't Hoen, a Dutch academic who has worked and made progress in this area. There might be opportunities for the committee to learn from their experience.

Deputy Bernard J. Durkan: We need to engage with our colleagues around Europe. Some countries are making efforts to avail of the benefits of the European market but for some unknown reason that has not gained traction and we have heard all the excuses. It has been the same old story for the past 20 or 30 years. That should not be; we should be able to record progress. It would be in the interests of the pharmaceutical companies if they want to supply a big market such as the United States and Europe, which is bigger than the US by a long shot. We need to encourage them in that direction in so far as we can. The European Commission

needs to do that as well. There is an opportunity for us to engage with our European colleagues on this issue because we have all believed for a long time that there is no other way to achieve this for patients who need particular treatment, other than through the benefit of the power of the European market. It cannot be done. Some pharmaceutical companies have larger budgets than some small countries in Europe.

Chairman: The present model is not sustainable because the number of drugs that will come onto the market over the next five years for rare and ultra-rare diseases, and for new cancer treatments, will be so costly that no health system can afford to supply them all. We need to change our model for dealing with pharmaceutical companies because it will be unaffordable. What is the benefit compared with other health initiatives, such as supporting people in the community, looking after frail elderly people at home, looking after our hospital structures and developing our new model of care, Sláintecare, which is in the doldrums at the moment?

Deputy Kate O'Connell: A few companies were saying that if there are 100 patients with X condition, they would put a top price on annual treatment, such that if there were 102 people, the two extra would be included in the bulk price. I ask the witnesses to expand on the matter. I see this as the market, yet again, ring-fencing a chunk of money so they can say to their shareholders: "We definitely have a return of €100 on last year's research." This element has emerged a bit recently with the orphan drugs. Do the witnesses think it is a good model to choose or not? What are the associated pros and cons of this approach?

Dr. Kieran Harkin: The model was used in Australia to fund hepatitis C treatment and I understand that it worked very well. They said: "We will treat on a population basis. We do not care how many people there are. Roll up as many as you want and we will actually offer the service." It was a successful model but I do not know what the relevant figure is. Having said that, we are saying it is a successful model because it might be, say, €10,000 per head compared with the initial price of €80,000. However, we know that it costs €100 to manufacture the hep C treatment. It depends on where one is coming from. It is a less bad option in some cases.

Dr. Ciara Conlan: They were well able to put it into the funding scheme.

Deputy Kate O'Connell: This is not my area of expertise. Is it true to say that the mechanism works if it is a population health issue like hepatitis, HIV, HPV or anything that one wants to eradicate?

Dr. Kieran Harkin: Correct, yes.

Dr. Ciara Conlan: Yes, to eradicate.

Deputy Kate O'Connell: Is it true to say that the mechanism would not necessarily be ideal for a small rare disease patient cohort?

Dr. Kieran Harkin: Yes.

Deputy Kate O'Connell: Obviously they have their sums done on this.

Dr. Kieran Harkin: Yes.

Deputy Kate O'Connell: Reference was made, by way of a response, to assessing the impact of treatment be it physiotherapy or home help. We seem to home in on the price of a drug and drug therapies. Obviously we want to cure illness but what about the spectrum between curing and not curing? I ask the witnesses to elaborate on the matter.

Dr. Kieran Harkin: I thought I picked up the matter from something that the Deputy said. Last year, we held our conference in the RCSI where a point was made by one of the health economists that there is a lot of research and comparing prices for drugs but there are other interventions like physiotherapy that nobody seems to think of actually doing. The point resonated with me and particularly when there are two patients, as the Deputy mentioned.

Deputy Kate O'Connell: Inequality is the thing.

Dr. Kieran Harkin: Yes, inequality. Let us say €0.5 million is being spent. We should say: "We have got this amount of money to spend on your care. Do you want it spent on this drug or on other things? Can we change your house? Can we get a special car for you? Can we supply you with a fitted aid?"

Deputy Kate O'Connell: Provide a package of care.

Dr. Kieran Harkin: If we have to say "this is the amount of money you have got to spend", then a lot of the time it will not be going the way of the drug company but, unfortunately-----

Dr. Ciara Conlan: I want to make it clear that we want Irish patients to have access to these drugs.

Dr. Kieran Harkin: Yes.

Dr. Ciara Conlan: We believe we can do better in getting a fairer price and that the opportunity costs within may not be so high, and we would be able to provide treatment. Dr. Harkin is a GP.

Dr. Kieran Harkin: Yes.

Dr. Ciara Conlan: There is a recent study that shows that physicians who feel they cannot provide adequate social services to their patients have much higher rates of burnout and we are all seeing that. We want to do so much more for our patients but we are very constrained.

Deputy Kate O'Connell: I thank the witnesses.

Chairman: I thank Mr. Robbie Lawlor, Dr. Kieran Harkin and Dr. Ciara Conlan for their expert views on the pricing of medicine and the availability of medicines both in Ireland and abroad. We will have a number other meetings on this topic and we will produce a report, hopefully, which would inform Government on developing a national drugs policy.

I propose that we adjourn the meeting until next Wednesday morning at 9 o'clock. Is that agreed? Agreed.

The joint committee adjourned at 11.55 a.m. until 9 a.m. on Wednesday, 13 March 2019.