Deputy Regina Doherty (Meath East, FG)

I welcome reform and innovation in health care and the pharmaceutical industry in particular. However, it is also important not to lose focus on how such reforms will affect the needs of particular patients. I add my support to the amendment proposed by Brainwave, the Irish Epilepsy Association. Professor Norman Delanty, director of the epilepsy programme in Beaumont, has stated that anti-epilepsy medications cannot be substituted by a generic drug without having profound consequences for the well-being of those who suffer from epilepsy. The doses of epilepsy medications are concentrated carefully for each individual to ensure good seizure control. Any variation may disturb the balance and result in an otherwise avoidable seizure, even if the active ingredient of the drug is not changed. This can have a major impact on the patient’s quality of life, as well as having clinical and financial implications to the primary and-or secondary health care system. Anti-epileptic drugs should not be subject to generic substitution and should be permanently excluded from any legislation introduced in the country.

Furthermore, the exclusion of anti-epileptic drugs from any new system of generic substitution was recommended in a report, entitled Proposed Model for Reference Pricing and Generic Substitution, and known as the Moran report, which was published jointly in May 2010 by the Department of Health and a HSE working group.

The campaign to exclude anti-epilepsy drugs from the Bill is supported by the entire epilepsy community and the health care professionals who treat and care for people with epilepsy. There is a model for this amendment as the United Kingdom, Austria, Belgium, the Czech Republic and Greece do not allow substitution of anti-epilepsy drugs for generics. Countries which have excluded many anti-epilepsy drugs from substitution include Denmark, Finland, Germany, Portugal, Spain, Sweden and Switzerland.

Over-spending on medications means the Government has less money to invest in other areas of health care. This legislation will have significant consequences for all stakeholders in the pharmaceutical supply chain. I am supportive of it but I appeal for the exclusion with regard to anti-epilepsy medication to be considered seriously. The patient must remain at the heart of our health care reforms.
Deputy Anthony Lawlor (Kildare North, FG)

I reiterate what Deputy Regina Doherty said about anti-epilepsy drugs. With other Deputies, I attended a talk given by Brainwave, the Irish epilepsy association. Minute changes in generic drugs can have a serious implication for people on long-term anti-epilepsy drugs. It is important that we take the fears of the association into consideration.

Deputy Finian McGrath (Dublin North Central, Indep)

My colleague referred to the Irish Epilepsy Association. It has argued that the substitution of branded epilepsy medicines with generic equivalents or switching from one generic to another generic version of the same drug can lead to a recurrence of seizures in some people whose epilepsy is otherwise under control. As part of the debate on cost saving we should take a broader view and I acknowledge the Government is doing so. One should listen to different vested interest groups. However, as someone who will promote patient issues, I am strongly supportive of the Irish Epilepsy Association and its arguments.

Deputy Catherine Murphy (Kildare North, Indep)

The object of the exercise should be to free up money which can be spent in the health service, particularly in delivering primary health care or front-line services. However, exceptions should be made for some areas such as anti-epileptic drugs. There can be a very fine balance for somebody with epilepsy in remaining free of seizures and to upset this could be very problematic. In 2010 we passed legislation relating to an EU directive on the length of time people must be seizure free before they are allowed to drive.

Included in this legislation are rules and regulations on changing medication. If one goes off one’s medication one must be instructed not to drive for perhaps six months. If one receives different medication it could produce breakthrough seizures where the previous medication used had been keeping someone free of seizures.

It is very important that an amendment is made to provide specifically for this. Often people do not return to a consultant or see a neurologist but instead they are maintained on their medication by their GP, who may not realise he or she cannot substitute. Failure to address this aspect could cause individual problems, and serious problems could also be caused for those using machinery, or people may have falls and present at accident and emergency departments.

The other point relates to those who are on drugs that suppress seizures. Sometimes these drugs can have other side effects where it is a matter of finding the right drug and finding the right balance. There might be a 10% tolerance in finding exactly the right balance and to upset that balance will be very problematic for potentially 40,000 people who are doing well. For example, the changes that occurred for those with epilepsy in the past 30 or 40 years have been immense. It has been a good news story for so many because it has given them back their independence. It has made them feel confident.
again because they can have some control over their lives. Often epilepsy takes away that control at key times in a person’s life, for example, when one is a teenager and has so much else going on. Recently, I was dealing with somebody where a youngster got a poor leaving certificate because she had epilepsy in that year, was going into college, was maintained on the drug and was doing well. We will spend a great deal putting that youngster through college but one wants her to go through at the best of her ability, and it is important to have her epilepsy controlled.

I cannot stress enough the importance of there being provisions in the Bill that allow for specific conditions such as epilepsy - I am sure it is not the only one. Such conditions will be the exception. Generics can contain very much the same ingredients and work well with most conditions, but conditions such as epilepsy are different. There are other countries that make exceptions when using generic drugs. Denmark, Germany, Portugal, Spain, Sweden and Switzerland all exempt epilepsy. Where there has been good reason to deviate, it makes for good health policy to do that.

Bernard Durkan (Kildare North, FG)

Earlier, I mentioned the issue of generic drugs versus drugs with brand names. In particular, I again emphasise that no one seeks to create a risk for patients. In the use of generics, it must be both possible and shown clearly that the patient being encouraged to use generics will have at least as good a product as the one that is brand-named.

Unless this is the case, the entire concept will be completely undermined because patient concern will become obvious. Moreover, on the points raised with regard to epileptic sufferers, where it has been presented that a particular brand has been found to be useful and has been consistent in terms of reaction and response, it should be used. However, it should not be allowed that the company should influence such a drug’s use or otherwise. The company obviously has its own reasons for making the case and it must be possible to be able to set out, purely on the basis of the ingredients, to ensure the same purpose can be served by the use of the generic products.

Alex White, Minister of State for Primary Care (Dublin South, Lab)

I will now turn to the crucial issue of safety of generic medicines. First, it is important that people are aware that generic medicines marketed in Ireland must be licensed and meet the requirements set down by the Irish Medicines Board in the same manner as originator medicines. Under the Bill, the Irish Medicines Board has responsibility for establishing and maintaining a list of interchangeable medicines, which will include both originator and generic medicines. In deciding whether to add a group of medicinal products to the list, the Irish Medicines Board must be satisfied that each medicinal product which falls within the group has the same qualitative and quantitative composition in each of its active substances as each of the other medicinal products which fall within the group; is in the same pharmaceutical form as, or in a pharmaceutical form that is appropriate for substitution for, each of the other products in the group; and has the same route of administration as each of the other medicinal products which fall within the group. In addition, the Bill provides that the board is not
permitted to add a group of medicinal products to the list of interchangeable medicinal products where, for example, any of the medicinal products cannot be safely substituted for any one or more of the other medicinal products in the group.

To enhance further the patient safety aspect of generic substitution, section 13 of the Bill allows a prescriber to indicate on a prescription that a branded interchangeable medicinal product should, for clinical reasons, not be substituted. A number of Deputies referred to the concerns raised by the organisation Brainwave with regard to generic substitution of epilepsy drugs. I am satisfied that the provisions in the Bill address concerns people may have with the safety of generic substitution, including those concerns raised by Brainwave. We are proposing to provide for a power of substitution, subject to a very strict regime, and there is no provision within the Bill constituting a direct decision to substitute a product. There is a provision for a power to be exercised by the Irish Medicines Board to introduce a substitution, which is an important distinction to be recognised by colleagues, particularly in the context of legitimate concerns about particular areas, such as people living with epilepsy. We will have the opportunity to tease out more detail on Committee Stage if colleagues bring amendments. The Bill does not in itself bring about any substitution but rather provides a legal framework within which the Irish Medicines Board may introduce substitution.

Any decision would be subject to a very rigorous regime. I repeat the key message that must be communicated by all associated with the implementation of generic substitution: generic medicines must meet the same quality and safety standards as originator medicines and have the same benefits and risks as originator medicines.

I wish to reiterate my commitment and the commitment of this Government to maintain and improve access to medicines for Irish patients. As I have stated, this needs to be done in the most cost-effective and efficient manner. The core objective of this Bill is to achieve value for money while maintaining and improving levels of service. By cost-effective I mean paying the most appropriate price for a particular product and there is no longer any justification, if there ever was, for paying a premium for a particular brand of medicine when an equivalent medicine, as assessed by the Irish Medicines Board, can be supplied at a much more competitive price.