

Health (Pricing & Supply of Medical Goods) Bill Report Stage Debate in the Dail

April 26th 2013

Summary of proceedings

Deputy Catherine Murphy (Ind)

Deputy Murphy said that while generic substitution is long overdue, its application in epilepsy would be a false economy. She spoke about how difficult it is to get epilepsy under control and the importance of keeping it that way. Epilepsy drugs are not “something that should be played with”. She spoke about the difficulties that would arise for a person who experienced breakthrough seizures having been substituted.

She also raised concerns about the ability of the Irish Medicines Board to properly evaluate or monitor what is being substituted in the community and reasoned that “without specialist oversight we may well cause problems for ourselves without any savings to the State in the longer term. It makes sense for the Government to step back. I make this appeal on behalf of 40,000 people”.

Deputy Murphy also spoke of the costs. These include the prospect of somebody losing his or her job and becoming dependent on the State, hospital treatment, risk to life, loss of independence because of not being able to drive and the side effects people experience when they change medicines. It could also cost the State. Most GPs would be unaware that they should write on a prescription that a substitution should not be provided. We are giving far too much responsibility to pharmacists and general practitioners in terms of the requirement to write particular words on prescriptions, she stated. The only way to achieve certainty is to exclude epilepsy drugs from this generic initiative, she concluded.

Deputy Murphy also referenced a Canadian study published in the journal Neurology which found that generic substitution of AEDs was significantly associated with negative outcomes, such as hospitalisations, injuries and increased health care costs. She asked why we were ignoring reputable, conclusive evidence such as this.

Deputy Billy Kelleher (FF)

Deputy Kelleher said that if the legislation is passed as it stands, people with epilepsy will not be able to trust their medication. There is genuine fear amongst the epilepsy community, he said. He pointed out that the people affected have been very genuine in their campaigning and noted that eminent consultants such as Prof. Norman Delanty have intervened for no other reason than concern for patients. He said that doctors “are pleading that what we propose be accepted.”

“We heard the passionate pleas and concerns to change this provision. Many of those with epilepsy have other challenges and now the Government is heaping extra ones on top of

them by undermining the security they should have in being guaranteed the same medicine that suits them and controls their condition”

He added that there is no concern about generic drug substitution generally but in the case of anti-epileptic drugs, there is a body of evidence against it and this has been recognised internationally.

He explained that he has met individuals who have epilepsy for whom huge advances have been made to manage their condition, and allow them to reach their full potential in work and life generally. The Bill, he said would represent a retrograde step in this regard.

Deputy Kelleher also referred to the Moran report and its recommendations to exclude AEDs from generic substitution. “We are now going down a route that is not accepted as best practice”, he said

Deputy Kelleher also highlighted the European Declaration on epilepsy which calls on the Member States to introduce appropriate legislation to protect the rights of all people with epilepsy. This legislation gives the Minister a golden opportunity to ensure that the rights of people with epilepsy are protected, he pleaded.

Deputy Caoimhghín Ó Caoláin (SF)

Deputy Ó Caoláin supported the amendment (suggested by Epilepsy Ireland) to include in the Bill a definition of "non-interchangeable medicinal products". The non-interchangeable products should be listed as well as the interchangeable ones, he argued as patients have an entitlement to the fullest information possible. He also said that there is a responsibility on the State and its agencies - in this instance the Irish Medicines Board - to provide all possible clarity on the suitability or otherwise of substitution. Legislators also have a duty to provide the greatest protections possible, he said.

In referring to the fears of people with epilepsy, he said that they were “absolutely justified based on the experience of epilepsy sufferers whose medication has been already substituted by pharmacists mindful of the change but unaware that it had not already come into play.”

Deputy Ó Caoláin also highlighted that generic variants of AEDs are not exact replicas and their use can have very negative consequences. Direct testimony from Epilepsy Ireland and from people with epilepsy who have suffered negative effects from unsuitable generic substitutes tells us this is a real issue rather than one that might happen, he insisted.

He said “I am deeply concerned that the Government is demonstrating that it is not willing to accept any change, that it knows best, that we are wasting our time going through a long examination of the minutiae of legislation, while offering, in good spirit, important, relevant and necessary amendments... Epilepsy Ireland has spent considerable time and, unquestionably, a significant part of its limited resources in a stoical effort to avert the problems that could present and which have already done so. I commend its efforts and record my disappointment that despite its sincere efforts, the necessary protections will not be built into the Bill.”

Deputy Róisín Shortall (Ind)

Deputy Shortall said that while she supports the Bill generally, she also supports the amendments proposed to safeguard the interests of people who suffer from epilepsy. While there are certain safeguards in place, such as the "do not substitute" clause, she said that "the Bill is not safe enough as far as people who suffer from epilepsy are concerned". She said that unsafe generic substitution is already happening and the legislation as drafted leaves open the possibility of further unsafe substitute medicines being prescribed for people who suffer from epilepsy.

She concluded "Does the Minister of State accept that it is not currently safe to substitute generic drugs for AEDs? If so, does the Department not have an onus to put in place the kinds of safeguards that are required? In the absence of those safeguards, one is depending on the individual patient's full awareness of his or her condition and the dangers associated with generic substitution. The patient would have to be very alert to the dangers associated with prescribed medications. One is also depending on all general practitioners being fully aware of the circumstances. That is not necessarily the case. We should also bear in mind locums, hospital prescribers and pharmacists. Everybody along the chain needs to be fully aware of the inherent or very real dangers of generic substitution of AEDs for people with epilepsy. That is a big ask. I do not have confidence that there is sufficient awareness throughout the prescribing chain."

Deputy Denis Naughten (Ind)

Deputy Naughten highlighted the volume of representation that TDs around the country have received on this issue from people with epilepsy or their families. He pointed out that while €75 million is spent annually on AEDs, €40 million of this is a drug prescribed almost exclusively to treat neuropathic pain. Those with epilepsy and their advocates have no disagreement with generic substitution being used for that purpose he said. The issue concerns medicines specifically prescribed to prevent seizures.

He said that the Bill puts the onus firmly on the individual with epilepsy. He questioned who is responsible if a GP does not specifically include the "do not substitute" instruction on a repeat prescription and the person with epilepsy does not realise that the medicine has been substituted and it leads to an adverse reaction?

We should not introduce legislation that will cause unnecessary concern and called for "a safety net to ensure that anyone with epilepsy can go in with confidence, have the prescription refilled and ensure they receive the exact same medicine".

"The argument has been made by Epilepsy Ireland that placement on a statutory footing would ensure there will be no risks along the prescribing chain... The Government should deal with this issue once and for all. It should provide certainty and confidence in the legislation so we can all endorse its passage" he stated. He also raised an alternative, which would be to make provision for a statutory instrument to be published in tandem with the legislation. This secondary legislation could specifically state that AEDs would not be deemed interchangeable.

Minister of State at the Department of Health, Deputy Alex White

Minister White opened by rejecting calls for a negative list of interchangeable medicinal products as suggested by Epilepsy Ireland. While some countries maintain a negative list, he stated it was not appropriate to do so here. "A positive list of interchangeable medicinal products is considered more desirable from a patient safety perspective" he said. Having met with Epilepsy Ireland, the Minister said that he had an appreciation of the issues involved and that he has genuinely considered this issue and discussed it on a number of occasions with officials.

However, he reiterated that the Bill in itself does not substitute medicines, merely put in place a regime to enable the IMB to consider whether it should substitute medicines in particular circumstances. He added that the expert body should have the trust of the House and of the public to do what it is required to do in accordance with the rigorous requirements set out in the Bill which it must honour and apply. Decisions on issues such as AEDs are matters for the Irish Medicines Board and he said he has no doubt that the board will have regard to the literature, experience and expertise available, as well as to the criteria set out in the Bill when it comes to making decisions.

In relation to the Moran report, the Minister said that this refers to medicines which, in general, will not be regarded as interchangeable including AEDs. The report does not call for a statutory exclusion of any medicine or group of medicines, he said.