

COMMITTEE ON HEALTH

Wednesday, 12 July 2017

[...]

Senator Rónán Mullen — I, too, thank the witnesses for their contributions. I wish to follow up on Senator Colm Burke's remarks. It appears that there is evidence of some type of scandal, moral or otherwise, here. We have the ironic situation that drugs that are sometimes manufactured here are available to people in other EU countries, and reimbursed by their governments, but they are not available to patients in Ireland. Can the witnesses explain what is at the root of the differentials? Ireland ranks extremely low compared with Germany, as Senator Colm Burke mentioned, France, England, Italy and Spain when one compares the access to orphan medical products. The figures show that 53 of the 148 licensed products are routinely available in Ireland. That is approximately one third. Vastly more of such treatments are available in Germany. Noting the irony that some of these drugs might well be manufactured in Ireland, what is the fundamental reason for that?

To move on from that, there is an EU regulation on orphan medicinal products. Is there a need to move to a European standard or a harmonisation where we accept drugs that are accepted, made available and funded in one member state for people who are in the very disadvantageous situation of having a rare disease? It is therefore much more difficult to do the types of tests for cost effectiveness involving these people. Should we be moving towards a kind of harmonisation and an acknowledgement that if a medicine is available in other states, it ought to be available here? Through the State-funded National Treatment Purchase Fund, people are able to access treatments unavailable in Ireland. It should follow that if licensed, proven medical products are available to people in other European countries, they should be available here.

The failure to progress aspects of the national rare disease plan is at the root of this issue. The plan dates back to 2014 and envisages a pathway for the assessment of the orphan medicinal products. What is the reason for the delay? Could the witnesses give a timeline for the activation of relevant sections of the plan in order that this problem can be tackled?

It is not just a matter of fewer products being approved. There is also a much greater delay for people to access new orphan therapies. It takes 50% longer than for traditional medicines. That adds to the unfairness faced by those suffering from rare diseases who, in many cases, will have a very short lifespan.

Mr Shaun Flanagan — Senator Mullen raised the issue of harmonisation and negotiations. One of the big challenges for harmonisation of decision-making is that not every country may be able to afford the same levels of investment. If a country is signing up to German levels of involvement, it must sign up to German levels of investment. Whether Ireland has those resources available to it as a State is a question I cannot clearly answer. It is a political question rather than a HSE one.

On the national disease plan, in terms of moving and changing the assessment processes around new drugs, as a public servant I would say the Health Act is clear. It has not made any changes that allow the HSE in any way to treat orphan drugs any differently to other drugs. If the view of the Oireachtas is strongly that there should be a separate process, there will be a requirement for legislative change. It is something we have to say. In terms of the 50% longer than ordinary delay in time on orphan drugs, there is no doubt orphan drugs are more challenging for an assessment body to consider. As the levels of evidence are on occasion less robust than they are for other medicines, they present challenges for decision-making bodies but they also come with significant budget impacts. Orkambi was for a rare disease but it came with a budget impact worth hundreds of millions over five years. Decisions to fund such drugs have implications for the rest of the service. Those are decisions that have to be made carefully after robust engagement from pharmaceutical companies on the price and offering they have made.

[...]

Senator Rónán Mullen — Can I just come in to clarify a few matters?

Vice Chairman — Very briefly, Senator Mullen. Other people are also trying to get in.

Senator Rónán Mullen — I understand that and I will be very brief. Is Mr. Flanagan saying that legislation would be needed to activate the OMP assessment pathway envisaged in the 2014 national rare disease plan? If not, are there any remaining obstacles? Is there unfinished work set out in the plan that ought to have been completed by now? Were

Ireland to match Germany in the provision of orphan medicines at the same price currently paid by the Germans, do the witnesses have an estimate as to how much that might cost?

Vice Chairman — I am going to ask Senator Mullen to hold his questions for now because other members have indicated and I know they are under time pressure.

[...]

Senator Rónán Mullen — Is there undone work that was envisaged in the 2014—

Vice Chairman — I must remind Senator Mullen that I am conscious there are people—

Senator Rónán Mullen — I did ask the question very specifically. A lot of other extraneous issues have been brought up here. I am dealing with the issue of orphan medicinal products. I asked the witnesses if there is undone work in terms of the 2014 national rare disease plan and if this is the case, why? I also want to know if Ireland were to provide the drugs on the same basis as is done in Germany, so that the same number of drugs of the orphan medicine would be available, what would be the extra costs? I imagine it is some percentage of €1 billion, but would the witnesses know what the figure is?

Vice Chairman — Can I ask the witnesses to keep their responses as brief as they can because I am conscious that there are very patient committee members also waiting to come in?

Mr. Shaun Flanagan — The simple answer around the question of pricing in Germany is that the information is not available. I can tell the Senator that on the basis of the products we have in front of us to consider, if we had €200 million we probably would not have enough money over the next five years to say "Yes" to everything. That is pretty clear.

On the question of undone work, Professor Barry has outlined the main finding. I am responsible for the application process for all new drugs. I am not responsible for the implementation of the rare diseases programme. I am not part of the rare diseases programme. I am operating outside of my comfort zone here; I am here to discuss the processes and criteria used when evaluating orphan drugs. It is my understanding that in respect of drugs the outstanding action in the plan is a separate process that would involve a rare disease committee.

Professor Barry has already described that and he has been asked to chair it.

Professor Michael Barry — The model of this committee is very much alongside the national cancer control, programme. When we do our assessments, for example, not only do we send our report to the HSE, we also send it to the national cancer control programme technology review group. That allows other stakeholders, especially clinicians with expertise in the area, to comment and to highlight unmet need or other areas that may not come out on a technology assessment. It is envisaged that the rare diseases technology review group or committee would behave in a similar manner. That would allow various stakeholders such as patients, patient groups, carers and clinicians to have a say in the process. We accept that ideally this would be done for everything.

Full discussion available at: <http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2017071200001?opendocument>