



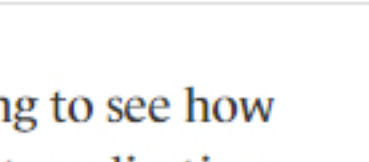
THEJOURNAL.IE The health minister said more women have applied for the drug that was expected.

SEVERE VOMITING

HSE review to allow GPs prescribe Cariban drug for pregnant women continuing, says minister

Stephen Donnelly confirmed that the budget allocation for the scheme will be surpassed.

13.6k 5 Apr 1st 2023, 7:30 AM



HEALTH MINISTER STEPHEN Donnelly has said work is ongoing to see how women who suffer from severe sickness during pregnancy can get medication through a GP prescription.

Speaking to *The Journal* yesterday in Mullingar, where he was opening a new ambulance centre, the minister said he still believes the best solution to problem is for it to become a licensed product.

The minister also confirmed that the €1.1 million allocation for the new scheme, which came into effect in January, will be surpassed due to the number of women applying for reimbursement exceeding expectations.

The drug, known as Cariban, was previously unavailable on the drugs payment scheme or medical card.

As part of a major campaign women impacted by severe vomiting – known as Hyperemesis Gravidarum or HG – called for the State to reimburse expenses for Cariban, which can cost up to €3,000 over the course of a pregnancy.

Budget 2023 set out that funding of over €1 million would be set aside to facilitate reimbursement of the drug, however, since its implementation this year, criticisms have been levelled at the barriers that have been created for women.

Last month, a consultant obstetrician at the National Maternity Hospital and assistant professor at UCD, Professor Mary Higgins said women experiencing severe vomiting illness during pregnancy are suffering from mental health issues, with some choosing not to continue with their pregnancy.

GP prescription

Hyperemesis is a “normal complication of pregnancy – a pretty horrible one” but GPs should be allowed to prescribe for the drug, argued Professor Higgins.

Currently, under the new Government scheme, women must get the initial prescription from a consultant and cannot get it from their GP. This is one of the main criticisms of campaigners and has resulted in the minister asking the HSE to review the situation.

The minister was blasted by Social Democrats Wicklow TD Jennifer Whitmore in the Dáil on Thursday, when she asked for an update on the HSE review, however, she was met with the same reply she received two months ago.



Jennifer Whitmore TD
@WhitmoreJen · Follow

Still no respite in sight for sufferers of [#Hyperemesis](#) as Minister rehashes the same info he gave me 2 months ago. No update on the HSE review...no new information...no sense of urgency...no respect for those waiting a HSE policy that actually works for them. [@HyperemesisIE](#)



TOPICAL ISSUE 4 HSE review of access to medication for sufferers of hyperemesis

8:33 PM · Mar 30, 2023 from Wicklow, Ireland

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Hyperemesis Ireland, a campaign group representing women with the illness, has criticised the minister for the lack of urgency, stating that two months after a review was announced, there has been no further information.

“Does a review even exist,” the group recently asked.

When asked for an update yesterday, Donnelly said the HSE is continuing its review, but provided no timeline as to when a solution will be found for women.

Applying for a licence

Due to Cariban being an unlicensed product (as the company has never applied for a licence), the minister said “ultimately, the sustainable resolution to this would be for the company to apply for the product to be licensed”.

Campaigners maintain that this is a moot point as there are a number of unlicensed products for other illnesses already covered by Drugs Reimbursement Scheme.

“We are looking at how we can bring it down to a GP prescription.

“What we want to see is, we want to see the company, I believe it’s a Spanish company, applying for a license and then we can simply process this the way we we process anything else,” he said.

“I’ve asked the I’ve asked the HSE to take a look at that,” he said.

Donnelly said he wants it to become “just completely normal for women in Ireland to be able to get this with a prescription from their GP and state funders,” he said.

When asked what the solution is if the company, with the encouragement of the HSE, still do not apply for a licence, the minister said:

“Well, let’s try and do that first. And it would be odd I think for them not to want to apply seeing as we’re doing this with them. But let’s see what other solutions might be required at that point.”

Budget allocation breached

As of 27 March, 847 applications for the drug reimbursement have been received, with 825 women approved for the drug.

Donnelly has said that the prescriptions are somewhat ahead of what was envisaged.

He told *The Journal* that the €1.1 million set aside in Budget 2023 will be exceeded, as a result.

“The run rate on the money allocations was higher than the allocation... so more of it was being prescribed than was expected,” said the minister.

He added “it’s not something we would want to cut off mid year” and budget allocations will be looked at again in the autumn.

The drug cost is also something the minister said the HSE is looking at, stating that in Ireland it retails for significantly higher than it does in some other European countries.

“For this to be sustainable, obviously we need to get value for money. And if other countries around Europe are paying significantly less for it,” he said, adding that bringing the price paid for the drug is something also being looked at.

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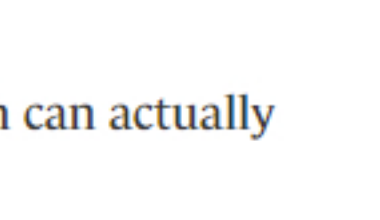
ALAMY STOCK PHOTO

SEVERE MORNING SICKNESS

Health Minister insists State won't reimburse cost of drug to treat severe pregnancy sickness

When Stephen Donnelly was in Opposition he told Simon Harris that the drug called Cariban should be available on the drugs payment scheme.

18.1k 14 Feb 4th 2022, 6:00 AM



DESPITE YEARS OF campaigning by pregnant women – as well as Health Minister Stephen Donnelly stating while he was in Opposition that a pregnancy sickness drug called Cariban should be available on the drugs payment scheme – it is still not being reimbursed by the State.

Over the course of a woman's pregnancy, the drug can cost between €1,500 and €3,000.

Between one in every 100 and one in 200 women suffers from severe vomiting, known as Hyperemesis Gravidarum or HG, which can profoundly debilitate women.

While many women suffer from regular morning sickness (which can actually occur at any time of the day) HG is a lot more serious.

Over the years, a number of politicians, including the current health minister, have said the drug should be available through the medical card also.

Donnelly in Opposition

In October 2018, Donnelly told the then-Health Minister Simon Harris that all costs including, appointments, specialised care, drug treatment and hospitalisation, which fall within the parameters of maternity care, should also be universally available.

In fact, he highlighted specifically a case of women who find they suffer from an extreme cases of vomiting who cannot get the very expensive drug on the medical card.

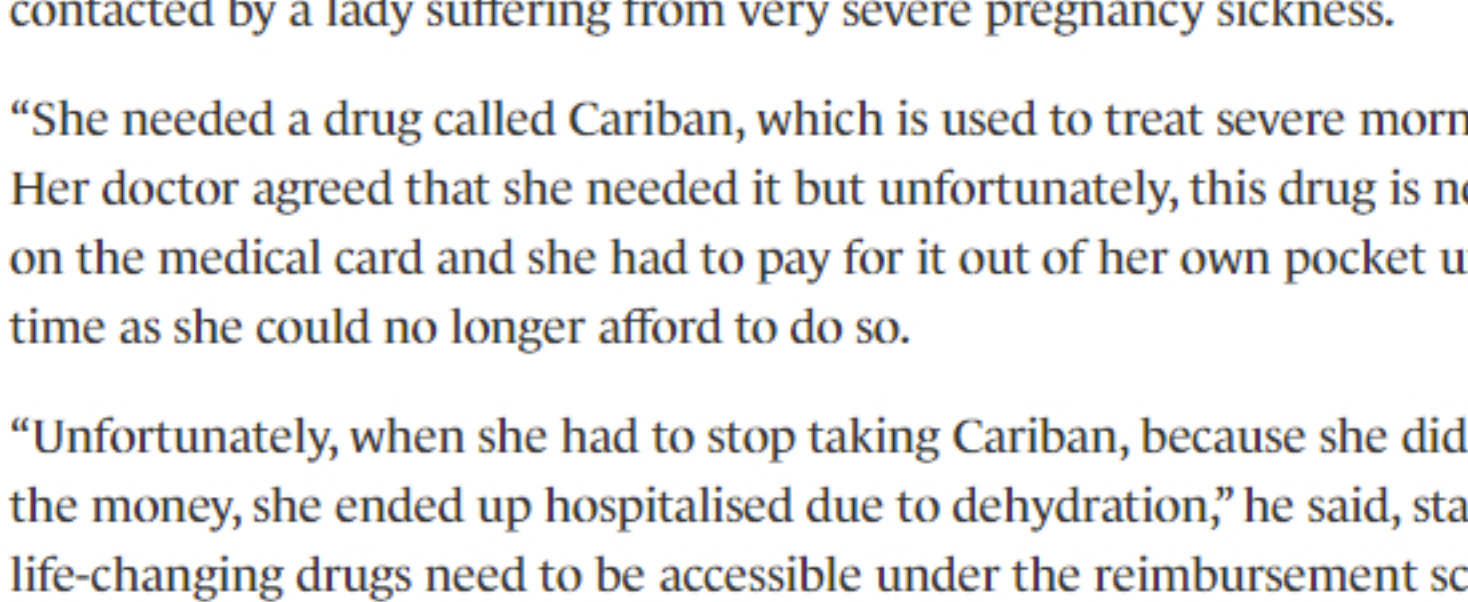
Cariban is prescribed and available in the Coombe, Rotunda and Holles Street maternity hospitals and has been for many years.

Fianna Fáil Senator Catherine Ardagh raised the issue in the Seanad last week, stating that there has been a huge campaign to get the State to reimburse the costs, "but to date nothing has been done by the HSE".

She called on the health minister to prioritise this issue and to outline what immediate actions they are taking to insure that women with hyperemesis do not face further financial hardship in accessing the basic HSE-recommended drug.

"The drug at the moment costs about €45 per week. That will need to be taken over the whole course of the woman's pregnancy. It is therefore a huge amount of money and it adds up. It is still not available.

"Women with morning sickness have been treated in a particular way since the 1960s. We are all aware of the Thalidomide drug scandal, whereby the drug brought on malformations in 10,000 children. We are now forgetting about these women again. Although it is only 1%, we have to do much more. The HSE needs to include this drug on the refund scheme," said Ardagh.



TD Thomas Gould also raised the matter in the Dáil recently, stating that he was contacted by a lady suffering from very severe pregnancy sickness.

"She needed a drug called Cariban, which is used to treat severe morning sickness. Her doctor agreed that she needed it but unfortunately, this drug is not available on the medical card and she had to pay for it out of her own pocket until such time as she could no longer afford to do so.

"Unfortunately, when she had to stop taking Cariban, because she did not have the money, she ended up hospitalised due to dehydration," he said, stating that life-changing drugs need to be accessible under the reimbursement scheme.

Women's experiences

In 2016, a number of [women told *TheJournal.ie*](#) about their experiences dealing with HG, and how Cariban was the only treatment to work.

A number of women spoke about the lack of understanding among the medical profession about HG, with many women stating they felt "unsupported, extremely sick and quite down".

One woman described how she was admitted and re-admitted to hospital, getting sick up to 20 times a day, while another said when she presented to hospital she was sent home with no help.

Another said her doctor told her to eat cold milk and Rice Krispies during her pregnancy. Later, when she presented to Holles Street Maternity Hospital emergency room, they prescribed Cariban to the woman.

"It's an expensive drug, but worth every penny. I took it for many weeks and then tried to come off it thinking I was through it, but as soon as I did the sickness and nausea came back. I went back on the drug and within days was perfect. The drug for me was effective and saved my sanity. I returned to work and got my life back," she told *The Journal*.

It is not just women and politicians who have been calling for action to be taken on the issue, medical professionals have also called for change.

Dr Mary Higgins from the National Maternity Hospital in Dublin previously told this website that having done training in Canada, she observed that nearly every woman suffering from this condition was on the medicine.

She explained Cariban, a vitamin B6 antihistamine, was first developed in the 1970s.

"It is the most studied pregnancy drug," said Dr Higgins, adding that studies have been carried out on more than 200,000 women.

'Unethical not to give it to women'

She said one published paper on the medicine goes so far as to say that it is now "unethical not to give it to women", adding that there still is a certain amount of a "put up with it" attitude out there.

"This condition can really make people miserable – it really comes down to quality of life while you are pregnant and some women simply don't have that when they have this condition."

The UK's biggest study into severe sickness during pregnancy was published last year. The impact, says the study, leads many to consider terminating their pregnancy, alongside 'suicidal thoughts'.

The report is released by King's College London, and the research was conducted by BBC News and Pregnancy Sickness Support.



In an answer to a recent parliamentary question on the matter from Sinn Féin's Pá Dáil, the health minister said the Health Products Regulatory Authority (HPRA) has advised that Cariban is currently not licensed for use in Ireland.

He said two similar products, Xonvea and Navalem have been licensed for use in Ireland.

The minister then stated that these two medicines are not readily available to women.

"The companies holding the authorisations/licences have not marketed the products in Ireland to date, and the HPRA cannot compel a company to market a medicinal product," he said.

"To be considered for a license in Ireland, the company marketing the product would need to make an application to the HPRA. After a thorough evaluation of all the supporting evidence, and if the benefits of the product outweigh the known and potential risks, a license may be issued," he said.

Drug Payment Scheme and medical card

"Where a medicine is not authorised in Ireland, a licensed wholesaler may import it if it has been prescribed by a doctor for a patient under his/her care, on his/her direct responsibility, and to meet the specific needs of a patient," said the minister.

"The decision to prescribe or not prescribe any treatment for an individual patient is a decision for the treating clinician, in consultation with their patient," he added.

Donnelly said the responsibility for the clinical use of unlicensed medicines lies with the prescriber, and they must ensure as far as possible that any treatment, medication or therapy prescribed for a patient is safe, evidence-based and in the patient's best interests.

"This applies equally to licensed and unlicensed medicinal products," said Donnelly.

In response to *The Journal* about what progress, if any, has been made in making this drug more available and affordable to women, the HSE said only licensed products are added to the reimbursement list in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

"The HSE does not reimburse medicines or agree reimbursement terms in advance of the completion of the required processes... the HSE advise that Cariban (doxylamine / pyridoxine) does not have a marketing authorisation from the HPRA or the EMA.

"Therefore, as Cariban is an unlicensed product in Ireland, it is not reimbursable under the community drug schemes. However, Cariban is currently prescribed in some maternity hospitals; if prescribed to an inpatient there is no charge to that patient."

As regards the drug Navalem, it said a pricing and reimbursement application has not been received by the HSE for this licensed product.

The HSE said it has received a pricing and reimbursement application for Xonvea, which is licensed.

However, the HSE states that in late 2021, the company responsible for the commercialisation of this product advised that they are not in a position to launch Xonvea in Ireland at this time.

"The HSE therefore cannot currently progress this application further within the national pricing and reimbursement processes," it said.

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The Journal



ALAMY STOCK PHOTO

BUDGET 2023

Cariban: Drug to help women who suffer severe pregnancy sickness to be available by January

Cariban is prescribed and available in the Coombe, Rotunda and Holles Street maternity hospitals and has been for many years.

8.6k 17 Sep 28th 2022, 5:37 PM



WOMEN WHO SUFFER from extreme sickness during pregnancy will get access to a life-changing drug free of charge by January, according to Health Minister Stephen Donnelly.

The drug, known as Cariban, is currently unavailable on the drugs payment scheme or medical card.

Women impacted by severe vomiting, known as Hyperemesis Gravidarum or HG, have called for the State to reimburse Cariban, which can cost up to €3,000 over the course of a pregnancy.

HG can profoundly debilitate those who suffer with it. While a majority of women experience regular morning sickness (which can actually occur at any time of the day), HG is a lot more serious and can often mean multiple hospitalisations.

Yesterday's budget set out that funding of €1 million would be set aside to facilitate reimbursement of drug.

Cariban will be fully reimbursed when prescribed by a consultant obstetrician for the treatment of Nausea and Vomiting during Pregnancy (NVP), *The Journal* has been advised.

However, questions have been asked by campaigners as to why their GP cannot provide the prescription.

Speaking to *The Journal* this afternoon, the health minister acknowledged those whose advocacy on the matter had put the issue "front and centre", stating that it is through this advocacy that the provision was included in Budget 2023.

"We are going to put the clinical pathways in place now," said Donnelly.

The minister said he sought a report from a specialised group within the Department of Health as to how it might work that this drug could be dispensed to women.

"What they have recommended at the moment is that it be made available on prescription from a obstetrician, from a treating obstetrician. I want to look at that now," he said, adding that some people are asking "legitimate questions" as to why their GP cannot prescribe the drug.

"We will also have to engage in negotiations with the suppliers [of the drug]," he added.

"The issue we have to address is, as it is not a prescribed medicine, we can't just add it to a list and drop it into an existing process," said Donnelly.

"So it is just going to take a little bit of time to reach agreement," he added.

Cariban is prescribed and available in the Coombe, Rotunda and Holles Street maternity hospitals and has been for many years.

However, one of the obstacles to the State reimbursing for the drug is the Health Products Regulatory Authority (HPRA) advised the minister that Cariban is currently not licensed for use in Ireland.

To be considered for a license in Ireland, the company marketing the product needs to make an application to the HPRA.

Where a medicine is not authorised in Ireland, a licensed wholesaler may import it if it has been prescribed by a doctor for a patient under his or her care.

The decision to prescribe or not prescribe any treatment for an individual patient is a decision for the treating clinician, in consultation with their patient, it is understood.

There were also issues in the past when the department classified the drug as a food supplement, something it later u-turned on.

Responding to whether €1 million will be enough funding as many women pay thousands for one course of the drug over the nine months of pregnancy, the minister said:

"What I can tell you is whatever is the amount of money that is required, that meet the clinical criteria, we will make that amount of funding available."

When asked when women can expect to have access to the drug, he said:

"Certainly I would hope to have that in place by January."

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