Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Duncan Smith, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

12th May 2023

PQ: 20405/23

To ask the Minister for Health if he will provide an update as of April 2023 on the production and publication of a review of the access and reimbursement issues surrounding the availability and access to the drug cariban; and if he will make a statement on the matter. -Duncan Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 20405/23), which you submitted to the Minister for Health for response.

As part of Budget 2023, the Minister announced €32.2 million in funding for Women's Health Initiatives in 2023, to include dedicated funding for Cariban® (doxylamine/pyridoxine). Cariban® is an Exempt Medicinal Product i.e. not licensed with the Health Products Regulatory Authority (HPRA) in Ireland. An exceptional arrangement was put in place effective 1st January 2023 to support the reimbursement of the Exempt Medicinal Product (EMP), Cariban® (doxylamine/pyridoxine), under the Community Drug Schemes (GMS and Drugs Payment Schemes) for the treatment of nausea and vomiting of pregnancy (NVP).

This product is made available on an individual patient basis for those patients who meet the criteria under the Community Drug Schemes (GMS and Drugs Payment Schemes) where Consultant Obstetrician initiated.

There are over 1200 applications from a number of maternity settings nationally, that have been received, processed and approved by the PCRS. Applications are being turned around in a short timeframe.

The HSE plan to carry out a preliminary desktop review of Cariban®. This will include engagement with clinical leads, the HSE Primary Care Reimbursement Service (PCRS) and relevant advocates.

As this medicine has been part of a reimbursement process since January this year it would be important to review the data over the course of the women's pregnancy. It is envisaged that this review will be completed by early July.

The HSE encourages clinicians, along with the Institute of Obstetricians and Gynaecologists and the National Programme for Obstetrics and Gynaecology, other healthcare professionals, and relevant representative bodies to encourage the market authorisation holders of the licensed medicinal products (Xonvea, Exelitis and Navalem) to progress with the formal pricing and reimbursement process in Ireland.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service