



Eoin O'Brien, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

6th April, 2021

PQ: 14304/21

To ask the Minister for Health if he plans to add cariban, xonvea and navalem to the approved drugs list under the drugs payment scheme; and the treatments available under the drugs payment scheme to treat hyperemesis gravidarum. -Eoin Ó Broin

Dear Deputy O'Brien,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14304/21), which you submitted to the Minister for Health for response.

Cariban (doxylamine / pyridoxine) is an unlicensed product that is not reimbursable under GMS and Community Drug Schemes. Only licensed products are added to the formal GMS Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

Xonvea® (doxylamine / pyridoxine) is the licensed product with the Health Products Regulatory Authority (HPRA) in Ireland. Xonvea is currently undergoing formal pricing and reimbursement assessment <http://www.ncpe.ie/drugs/doxylamine-pyridoxine-xonvea/>. To date, a pricing and reimbursement application has not been received by the HSE for Navalem®(doxylamine / pyridoxine) which is also licensed by the HPRA in Ireland.

Under the legislation there are formal processes which govern applications for the pricing and reimbursement of medicines. The HSE does not reimburse medicines or agree reimbursement terms in advance of the completion of the required processes. The HSE does not intend to reimburse Cariban under Community Drug Schemes or review the clinical evidence for this unlicensed product. As there is a licensed product (Xonvea®) available in Ireland going through the formal process, the clinical evidence for this product will be examined as part of the national pricing and reimbursement assessment

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle'.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service