



Martin Browne, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

10th March, 2021

PQ: 11034/21

To ask the Minister for Health his plans to approve medicines for the treatment of hyperemesis gravidarum for medical card patients and the drug payment scheme (details supplied). -Martin Browne.

The recommended treatment for hyperemesis gravidarum in Ireland is medication that is not available on the medical card and can cost several thousand euros over the course of a pregnancy as a result.

Dear Deputy Browne,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 11034/21), 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', written over a thin horizontal line.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service