



Gary Gannon, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

11th March, 2021

PQ: 12148/21

To ask the Minister for Health if unlicensed prescription medications are available on the drugs payment scheme in circumstances in which licensed versions are not currently available or marketed in Ireland; and if licensed medications for hyperemesis gravidarum are currently available and marketed in Ireland. -Gary Gannon.

Dear Deputy Gannon,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 12148/21), 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,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie