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Mark Ward, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

29th October 2021

PQ: 50185/21

To ask the Minister for Health if he has given consideration to frontline treatment for hyperemesis to be included on the drug payment scheme and the medical card scheme; and if he will make a statement on the matter. -Mark Ward

Dear Deputy Ward,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 50185/21), 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.

In terms of the specific details of the application for the pricing and reimbursement of doxylamine / pyridoxine (Xonvea®):

- The HSE received a pricing and reimbursement application for doxylamine / pyridoxine (Xonvea®) tablets on the 23rd July 2019 for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process for this medicine on 23rd July 2019

- A rapid review assessment was completed by the NCPE on 15th August 2019 in line with agreed processes. The NCPE advised that "A full Health Technology Assessment is not recommended. The NCPE recommends that doxylamine / pyridoxine (Xonvea®) not be considered for reimbursement at the submitted price"

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications

- The CPU reviewed the NCPE rapid review assessment report and remains available to meet with the applicant company to discuss issues arising from the report. To date no meeting has been arranged. CPU has recently made contact with the company responsible for commercialization of this medicine to request an update on whether it intends to proceed with the application for pricing and reimbursement of Xonvea®. CPU currently await a formal response regarding same.

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The rapid review report will be reviewed by the HSE Drugs Group, along with any outputs of commercial negotiations, and any patient group submission(s) received

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new uses of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013

The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service