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David Cullinane, T.D.
Dáil Éireann,
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11th May 2022

PQ: 21123/22

To ask the Minister for Health the status of a clinical review by the HSE Medicines Management Programme for cariban; if there is a timeline for a decision on the recommendation to be made; and if he will make a statement on the matter. -David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 21123/22), 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.

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 has received and reviewed the NCPE rapid review assessment report. https://www.ncpe.ie/drugs/doxylamine-pyridoxine-xonvea/

- CPU has made contact with the company responsible for commercialization of this medicine to request an update on whether it intended to proceed with the application for pricing and reimbursement of Xonvea®. The company has recently responded to outline that they are not in a position to commercially launch Xonvea® in Ireland at this point in time.
- The HSE Corporate Pharmaceutical Unit consider that the pricing and reimbursement application for Xonvea® is now closed.

To date, a pricing and reimbursement application has not been received by the HSE for the licensed product Navalem® (Doxylamine / Pyridoxine).

To date, a pricing and reimbursement application has not been received by the HSE for the licensed product Exeltis® (Doxylamine / Pyridoxine).

It should be noted that in reviewing the Summary of Product Characteristic (SPC) for the licensed products – Xonvea®, Navalem® and Exeltis®, it states "there is limited evidence in cases of hyperemesis gravidarum for the combination doxylamine/pyridoxine. These patients should be treated by a specialist."

As the pricing and reimbursement process has now closed, the HSE asked the Medicines Management Programme to examine the appropriateness and feasibility of a patient specific arrangement for the product. The HSE Medicines Management Programme assessment for Cariban (doxylamine/pyridoxine) has now been completed and its recommendation is under deliberation with the HSE at present.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service