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**BY EMAIL ONLY**

Deputy Pádraig Mac Lochlainn  
Dáil Éireann  
Leinster House  
Kildare Street  
Dublin 2

5th March 2024

**PQ53579/23- Deputy Pádraig Mac Lochlainn-To ask the Minister for Health if the drug phesgo can be administered by general practitioners; and if he will make a statement on the matter.**

Dear Deputy Mac Lochlainn,

Thank you for your representation.

Phesgo® is a fixed dose subcutaneous injection combination of two cancer medicines which are approved and funded by the HSE i.e. Trastuzumab and Pertuzumab. Phesgo® is a new combination formulation containing both drugs that can be administered subcutaneously as a fixed dose.

In December 2022 Phesgo® was approved for reimbursement under the Oncology Drug Management System (ODMS) for the following licensed indications:

- In combination with chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.
- and
- In combination with Docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

As per the summary of product characteristics (SmPC) for Phesgo®, the method of administration details *“Phesgo should only be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. Phesgo should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation facilities are immediately available”*.

[https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_en.pdf)

Where a licensed medicinal product is suitable (as per the product licence and criteria in line with the Health (Pricing and Supply of Medical Goods) Act 2013:) for self-administration or administration by a carer (i.e. not requiring administration or supervision of administration by



a Health Care Professional) it may be considered eligible for inclusion under the Community Drug Schemes.

I hope this provides you with some assistance.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sharon Hayden', with a large, sweeping flourish at the end.

Sharon Hayden  
General Manager  
Office of the Chief Clinical Officer