



Duncan Smith, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

16th December 2022

PQ: 61501/22

To ask the Minister for Health if a higher reimbursement price is granted to unlicensed medicines than the licensed version of the same medicine; and if he will make a statement on the matter. -Duncan Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 61501/22), which you submitted to the Minister for Health for response.

Companies (Marketing Authorisation Holders) are required to submit pricing and reimbursement applications to the HSE for consideration.

Medicines are added to the formal Reimbursement List following detailed assessments which include assessment of the clinical evidence, the economic evidence and the budget impact of a decision to reimburse specific indications of a medicine. The Primary Care Reimbursement Service is required to reimburse in line with approved decisions of the HSE and the HSE is required to formally assess each medicines and each specific use of such medicines before reimbursing them. Medicines are added to the Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013 with an agreed reimbursement price.

Where there is a shortage of a product on the Reimbursement List, the company can make arrangements for a temporary code of the same product (Batch Specific Request (BSR) as approved by the Health Products Regulatory Agency (HPRA)) to cover supply to the market during the shortage period. The price agreed by the HSE for the BSR is pro-rata pricing.

Where a product shortage occurs, there is no licensed therapeutic alternative and the supplier, does not make arrangements for a temporary code with the HSE, reimbursement support for the EMP is available, provided that the price is not excessive (i.e. the cost should

be reasonable in the context of schemes). Temporary codes can only be issued where there is an agreed supplier and price.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Suzanne Doyle', written in black ink on a white background.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service