An Bille Sláinte (Earraí Liachta a Phraghsáil agus a Sholáthar) (Leasú), 2021
Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2021

Meabhrán Míniúcháin
Explanatory Memorandum

AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR) (LEASÚ), 2021

HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) (AMENDMENT) BILL 2021

EXPLANATORY MEMORANDUM

Background

The purpose of the Bill is to amend the Health (Pricing and Supply of Medical Goods) Act 2013 (the Principal Act) to put in place a structure for the Health Service Executive (HSE) to appropriately assess orphan medicinal products (OMP) when making a relevant decision regarding adding an item to the Reimbursement List.

It will provide clear guidance to the HSE over the appropriate usage of Health Technology Assessment guidelines when assessing an orphan drug, as well as establish new criteria for the HSE to consider when making a relevant decision.

The Provision of the Bill are set out under four sections:

Section 1 sets out to define the term 'orphan medicinal product',

Section 2 inserts same into the Principal Act. The definition used is that set out in the Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

Section 3 amends section 19 of the Principal Act. Section 19 of the Principal Act deals with the HSE's decision-making process in adding medical items to the Reimbursement List. Section 19(5) establishes that the HSE shall have regard to Health Technology Guidelines published by the Health Information and Quality Authority (HIQA) that appear relevant.

Presently, the HSE does not differentiate an orphan medicinal product from other medicines in assessing the cost effectiveness of a medicine seeking reimbursement. Presently, health technology assessments place a heavy emphasis on fixed thresholds on the financial value of the volume and quality of increased life expectancy a treatment provides (a Quality Adjusted Life Year). Threshold incremental cost-effective ratios disadvantage orphan medicinal products, due to the often low available quantitative data (as a rare disease, by definition, affects a small patient population), while orphan medicinal products treat life-threatening or chronically debilitating diseases, meaning the improvements in health outcomes will be proportional to the severity of the patient population (i.e. the incremental cost-effective ratio will often be high).

Section 3 of this Bill amends subsection 5 to qualify that, for the avoidance of doubt, any HIQA guidelines that include a threshold incremental cost-effective ratio (ICER) or similar assessments shall not

be considered relevant when considering an orphan medicinal product for reimbursement.

Section 4 amends schedule 3 of the Principal Act. The Principal Act sets out criteria under Schedule 3 against which all medicines must be considered by the HSE when making a relevant reimbursement decision. Part 3 (General Criteria) of this schedule contains several criteria against which orphan medicinal products are particularly unfairly disadvantaged – given their typically low patient population profile, high individual cost and low budgetary impact.

Accordingly, Section 4 establishes a new set of criteria for consideration of orphan medicinal products, mitigating against low quantitative data and guaranteeing that the HSE will consider qualitative data presented on an orphan medicinal product from patients, clinicians and others. Section 4 also aims to tackle inequity of treatment for patients with rare diseases by legislating for consideration of unmet need and the availability of the same treatment elsewhere in the European Union. Additionally, Section 4 would require the HSE to consider the level of certainty provided via risk-sharing commercial agreements with the manufacturer of the orphan medicinal product.

Padraig O'Sullivan TD,
Deireadh Fómhair, 2021.

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