Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Colm Burke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

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PQ: 37819/22

To ask the Minister for Health if Ireland is currently in breach of the European Union Transparency Directive 89/105/EEC; if his Department intends to reduce the ongoing delays for patients to gain access to European Medicines Agency-approved medicine in Ireland; and if he will make a statement on the matter. -Colm Burke

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 37819/22), which you submitted to the Minister for Health for response.

The HSE is the national authority with responsibility for the pricing and reimbursement of new medicines or new uses of existing medicines. The legislation underpinning the National Application, Assessment & Decision Process for new medicines is the Health (Pricing and Supply of Medical Goods) Act 2013 and the design of the 2013 Act complies with the requirements of the Directive.

The 2013 Act transparently sets out details of the criteria that the HSE must consider when making decisions in relation to pricing and reimbursement.

Prior to making any decision regarding funding / reimbursement of a medicine, the HSE must have regard to the following criteria as set out in Schedule 3 (Part 3) of the 2013 Act:

(a) The health needs of the public,
(b) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(c) The availability and suitability of items for supply or reimbursement,
(d) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(e) The potential or actual budget impact of the item or listed item,

(f) The clinical need for the item or listed item,
(g) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(h) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and
(i) The resources available to the HSE.

The HSE is required to consider the following criteria when it is making decisions in relation to pricing of Medicines:

(*a*) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,
(*b*) the relevant prices of therapeutically similar listed items,
(*c*) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,
(*d*) the potential budget impact of the item if it were to become a listed item,
(*e*) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
(*f*) the resources available to the Executive, and
(*g*) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.

The 2013 Act and the IPHA Agreements (which are published) provide the necessary transparency in relation to the design of the pricing and reimbursement processes, which are set out below.

An application to have a medicine added to the Reimbursement List or to be priced as a hospital medicine, together with any relevant fees and a Rapid Review Assessment dossier and HTA dossier (as appropriate), can be submitted to the HSE as soon as the market authorisation has been granted. In fact, the HSE enables companies to commence part of the application process (i.e. the assessment processes), provided the companies have formulated a decision in relation to the price for which they intend to apply, on receipt of a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), which generally is 2 to 3 months prior to when a market authorisation is granted.

The 2013 Act (in compliance with the Directive) allows for the operation of stop clocks during the application process whilst the HSE is awaiting information from the applicant company.

The National Centre for Pharmacoeconomics (NCPE) plays a pivotal role in assisting the HSE with the assessment of all new medicines. Since September 2009 following receipt of an application for reimbursement the cost-effectiveness of all new medicines are considered prior to a decision being made by the HSE. All applications will be subjected to a preliminary rapid review. High cost products and those with an associated significant budget impact will be subjected to formal pharmacoeconomic assessment.

The NCPE endeavours to issue a Rapid Review Assessment report within four weeks of receipt and issue the formal pharmacoeconomic assessment (i.e. HTA report) within 90 days (allowing for the 'stop-clocks' process). When the HSE receives a Rapid Review Assessment report or HTA report it endeavours to consider that report within 14 days in conjunction with the criteria set out in the 2013 Act. A final decision can thereafter be reached for

certain medicines and will be duly notified to the Company. In the event that additional information is required to enable a decision to be made the HSE engages with the relevant company to seek same.

Following engagements with a Company, a medicine may be required to be submitted for consideration by the HSE Drugs Group (the "Drugs Group"). The HSE endeavours to advise the Company in writing of the recommendation of the Drugs Group within 14 days of the making of that recommendation. This recommendation will be commercially confidential between the HSE and the relevant Company to enable appropriate due process to be completed.

Recommendations from the Drugs Group are considered at the next HSE Executive Management Team meeting and the HSE endeavours to make a decision on the application within 45 days of the Drugs Group recommendation. The output of the consideration by the HSE Executive Management Team may result in:

a) a decision to reimburse at the applied terms,
b) a decision not to reimburse at the applied terms, or,
c) a requirement to meet with the applicant Company to address any issues arising or to seek clarifications.

Where the HSE approves an application to reimburse a medicine, reimbursement will be implemented within 45 days. On such approval, and where the application for reimbursement was made pursuant to the 2013 Act, the medicine will be added to the Reimbursement List and will specify the price at which the medicine will be eligible for reimbursement. The HSE publishes updates to the list of reimbursable items on its website monthly. The Reimbursement List is publicly accessible at: http://www.hse.ie/eng/staff/PCRS/items/

In compliance with the Directive, where the HSE is minded to make a decision to not accept a price or to not approve reimbursement the 2013 Act requires the HSE to issue a formal notice of proposal of same, setting out the proposed decision, the reasons for the proposed decision and to make clear that the applicant has the right to make representations in writing in relation to this proposal and the time frame for such representations (which must be at least 28 days). The HSE is obliged to consider any representations received before making a decision. In the event that the HSE does make a decision to not reimburse it is obliged to provide notice in writing, to set out the reasons for the decision and to provide copies of all expert opinions or recommendations considered. The 2013 Act (again in compliance with the Directive) sets out that an applicant may appeal any decision of the HSE to the High Court.

The HSE endeavours to provide access to as many medicines as possible within the resources provided to it and in as timely a fashion as possible. The HSE is working on certain improvements identified during the negotiation of the Framework Agreements with Industry in 2021, including a number of enhancements in the application process and further transparency around the application process. These enhancements were committed to by the State so as to assist with the timely processing of applications for pricing and reimbursement.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service