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Louise O'Reilly, T.D.
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Leinster House,
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10th March, 2021

PQ: 9998/21

To ask the Minister for Health if he or the HSE have considered alternative drugs and treatment plans for patients in the absence of the approval of a drug (details supplied). - Louise O'Reilly.

Partisan (Onpattro®) for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis).

Dear Deputy O'Reilly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9998/21), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible in as timely a fashion as possible from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

In terms of the specific details of the application for pricing and reimbursement of Patisiran (Onpattro®):

The HSE received an application for pricing / reimbursement of Patisiran (Onpattro®) on the 7th December 2018 from Alnylam (the applicant) for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process on the 7th December 2018. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE (3rd January 2019) that a full Health Technology Assessment (HTA) was required for this medicine

- The HSE commissioned a full Health Technology Assessment on the 9th January 2019 as per agreed processes

- The NCPE Health Technology Assessment report (http://www.ncpe.ie/wp-content/uploads/2019/01/Technical-summary-document-patisiran-21.02.2020.pdf) was received by the HSE on the 24th February 2020. The NCPE recommended that Patisiran (Onpattro®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. CPU engaged in commercial negotiations with Alnylam in May 2020 regarding their application for Patisiran (Onpattro®)

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. Patisiran (Onpattro®) was considered at the additional meeting of the Drugs Group in July 2020. The final HTA report was reviewed by the HSE Drugs Group, along with the outputs of commercial negotiations, and the patient group submission received during the HTA process. The Drugs Group requested Patient and Clinician Engagement input via the Rare Diseases Technology Review Committee (RDTRC) to assist the group in making its recommendation to the HSE Executive Management Team (EMT) regarding reimbursement of Patisiran

- The RDTRC Statement on Patisiran (Onpattro®) was received by the HSE on the 26th November 2020. The CPU met with the applicant company in December 2020 and early January 2021 for further discussions that also included deliberations on the pricing position

- The HSE Drugs Group considered in detail at its January 2021 meeting the relevant documentation in relation to Patisiran (Onpattro®), including the additional information provided by the RDTRC Statement. The HSE Drugs Group found itself unable, at this juncture, to recommend in favour of reimbursement of Patisiran (Onpattro®) for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) on its review of all of the criteria it had a responsibility to consider. Further detail on the considerations of the Group for this application is available from the minutes published online https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-january-2021.pdf

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new uses of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013

- Where the HSE EMT has considered a recommendation of the Drugs Group, and when circumstances arise where it is minded to accept a Drugs Group recommendation of non-reimbursement, the HSE is required (in line with the Health [Pricing and Supply of Medical Goods] Act 2013) to set out in detail a notice of any proposed decision to an applicant company. The HSE where such circumstances apply, is also required to provide at least a 28 day period (from the formal written notice of proposal) to enable an applicant company to consider any such proposal not to reimburse and to make representations to the HSE where it is so minded. The HSE is required to consider any such representations in advance of a formal decision being issued to the applicant company

- In advance of issuing the formal notification of the proposed decision not to support reimbursement of Patisiran for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) the CPU met with the applicant company on the 5th of February 2021 to discuss the HSE EMT proposed decision and the next stages of the assessment process. The formal notification of the proposed decision was subsequently issued to the applicant company

- Alnylam submitted representations on the 5th March 2021 in response to the formal notification of the proposed decision of the HSE not to support reimbursement of Patisiran (Onpattro®) for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy

- The representations will be reviewed by the Drugs Group who will then make a recommendation to the HSE EMT on the basis of all of the available evidence in line with the Health (Pricing and Supply of Medical Goods) Act 2013

Until the time when the assessment process has concluded and a formal decision has been communicated to Alnylam (the applicant), the application for reimbursement remains under consideration with the HSE. The HSE cannot comment on possible outcomes from the ongoing process or advise on individual cases and individual treatment plans for patients.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service