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

18th May 2022

PQ: 21933/22

To ask the Minister for Health the health technology assessments received by the Corporate Pharmaceutical Unit in each of the years 2018 to 2021 and to date in 2022; the date of the HSE Drugs Group decision; the date of reimbursement in tabular form; and if he will make a statement on the matter.

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 21933/22), 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 using the resources available (provided) to it. In doing so, the HSE robustly assesses applications to ensure available resources can be stretched as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

There are formal processes which govern the pricing and reimbursement of medicines and the application process for new medicines to be funded and / or reimbursed.

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

The HSE considers a pricing application for indicated uses in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE considers the following criteria prior to making any decision on funding / reimbursement:

(1) The health needs of the public,
(2) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,
(4) 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,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,

(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) 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
(9) The resources available to the HSE

The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to pricing and reimbursement applications for medicines. Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the list of reimbursable items / funded via hospitals. This process frequently involves the submission of a clinical and economic dossier to the National Centre for Pharmacoeconomics (NCPE) as part of the pricing and reimbursement application. The HSE CPU commissions the NCPE to conduct health technology assessments (HTAs) of medicines. The NCPE uses a decision framework to systematically assess whether a medicine is cost-effective as a health intervention. The NCPE makes recommendations on reimbursement to assist HSE decisions. The details of all HTAs conducted between 2018 to 2022 are publicly available on the NCPE website: https://www.ncpe.ie/pharmacoeconomic-evaluations/all-drug/

The HSE Drugs Group is a national committee and it is tasked with providing a recommendation to the HSE Executive Management Team (EMT) in relation to the pricing and reimbursement of new medicines. It considers all of the criteria in the Health (Pricing and Reimbursement of Medical Goods) Act 2013. The minutes of the HSE Drugs Group meetings are published and publically available online: https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/. The HSE Drugs Group recommendation for each medicine reviewed is also included in the published minutes.
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.

Information on reimbursement of medicines included under the Community Drug Schemes and under High Tech Drug Arrangements is available from the Primary Care Reimbursement Service (PCRS) website. The reimbursement list does not detail the licensed or approved indication for each medicine included. An update on the reimbursement list is published towards the end of each month and will include relevant changes including new additions for reimbursement under the schemes. For a new addition (i.e. approval) to be included on this update the applicant must have liaised with PCRS to confirm the launch of the product. The update and reimbursement list is accessible on the PCRS website:
https://www.hse.ie/eng/staff/pcrs/online-services/
https://www.sspcrs.ie/libr/html/monthlyproductupdate.pdf

The accompanying PDF document details the list of new medicines and new uses of existing medicines reimbursed between 2018 to 2022 (to date) which have been subject to a full Health Technology Assessment (HTA).

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service