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Bernard Durkan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd December 2021

PQ: 59756/21

To ask the Minister for Health the current or proposed regime governing new or orphan drugs; the number of such drugs under review or examination at the moment; the number to be approved in the course of the next year; the extent to which reimbursement will be in line with demand; and if he will make a statement on the matter. -Bernard J. Durkan

Dear Deputy Durkan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 59756/21), which you submitted to the Minister for Health for response.

Note on medicines for rare diseases: *The Committee for Orphan Medicinal Products (COMP) is the European Medicines Agency's (EMA) committee responsible for recommending orphan designation of medicines for rare diseases. This designation is for medicines to be developed for the diagnosis, prevention or treatment of rare diseases that are life-threatening or very serious. In the European Union (EU), a disease is defined as rare if it affects fewer than 5 in 10,000 people across the EU. The European Commission decides whether to grant an orphan designation for the medicine based on the COMP's opinion. The HSE CPU does not maintain a register of medicines for rare diseases and/or designated orphan medicines as the orphan status for a medicine is subject to change (i.e. may be removed from the Community Register of designated Orphan Medicinal Products). As outlined above, the appropriate repository for this information is the EMA website (https://www.ema.europa.eu/en).*

The number of pricing and reimbursement applications for new medicines (or new uses of existing medicines) with orphan status as of the 14th December 2021 is 26. This number is a point in time estimate only and may fluctuate daily depending on changes to the orphan status of a medicine, submission of new pricing and reimbursement applications to the HSE, and approval of pricing and reimbursement applications by the HSE.

There is a National Application, Assessment & Decision Process for new medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around new medicines. The Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and considering pricing and reimbursement applications from the pharmaceutical industry.

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 first involves a company making an application and submitting a clinical and economic dossier to support its pricing and reimbursement application. That dossier is reviewed by experts at the National Centre for Pharmacoeconomics (NCPE). The NCPE then provides a report to the HSE in relation to the company dossier. The NCPE process also enables the provision of a Patient Interest Group Submission. The NCPE uses a decision framework to systematically assess whether a drug is cost-effective as a health intervention. The NCPE makes recommendations regarding reimbursement to assist HSE decisions.

The HSE must then consider the report and the pricing & reimbursement application from the company. Frequently the HSE Corporate Pharmaceutical Unit will engage with companies to discuss and explore solutions to issues raised in NCPE reports.

The HSE has a national committee, the HSE Drugs Group, which is set up to provide advice to the HSE Executive Management Team (EMT) arising out of the information included in the NCPE report, the company response, patient interest group submission and any commercial discussions. The responsibility of the Drugs Group is to make a recommendation in relation to each individual application having considered the criteria set down by the Oireachtas in relation to the pricing and reimbursement of new medicines.

The HSE must consider 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

Final Decision making is reserved to the HSE Executive Management Team (EMT). 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 use 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.

The €30m allocated in Budget 2022 will enable the HSE to continue to fund new medicines and new uses of existing medicines (including medicines with orphan status), in line with the national process outlined above.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service