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Michael Healy Rae, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

20th October 2021

PQ: 48600/21

To ask the Minister for Health the breakdown of the €50 million allocated to the provision of new medicines (details supplied); and if he will make a statement on the matter. - Michael Healy-Rae

Minister on the 28th Sept 2021 during a response to a topical issue you stated that the Governments allocation of €50million for new medicines in Budget 21 has enabled the HSE to approve 32 new medicines or expand its use of existing medicines to date this year. You went on to say this has included 12 medicines for the treatment of rare diseases. My question to you is as follows out of the allocation of €50 million can I please get a breakdown of exactly where it has been spent? and has every euro of this €50million actually been committed or is there money left because to be frank what I am after is the necessary funding that are required for the two children in Ireland who are in urgent need of the drug Zolgensma.

Dear Deputy Healy Rae,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 48600/21), 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 statutory processes which govern the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

In line with these statutory processes, in October 2021 the HSE approved the reimbursement of Onasemnogene abeparvovec (Zolgensma®). Reimbursement is restricted to the following subgroup of the licensed population: *Patients with SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type I, or pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene*. The approved subgroup is in line with the application from the applicant (Novartis Gene Therapies), who had applied for reimbursement for the restricted population outlined above. Prescribers will be required to apply for reimbursement approval on an individual patient basis.

Regarding the breakdown of the €50 million allocated for new medicines in 2021, the HSE is unable to reveal the breakdown of expenditure for each drug. The HSE, as standard, engages in commercial negotiations with drug manufacturers to ensure the HSE delivers the best possible prices for new drugs. The HSE has made commitments on behalf of the State in relation to the maintenance of commercial confidentiality underpinning many of the drugs approved in 2021. Any breach of such commercial terms exposes the State to the risk of commercial litigation and would compromise the State's ability to achieve the best prices possible.

The HSE continues to accept and consider applications for the pricing and reimbursement of medicines, and new uses of existing medicines, in line with the formal statutory processes.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service