



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

4th February, 2021

PQ: 4345/21

To ask the Minister for Health the number of reimbursement applications currently being processed in respect of orphan new drugs; the length of time to deal with individual applications; 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 4345/21), which you submitted to the Minister for Health for response.

Note on orphan drug status: 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 drugs as the orphan status for a drug 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>).

As of the 1st February 2021, there are currently 91 medicines in process (includes new drugs and new indications of existing drugs) of which 26 have an Orphan Drug Designation.

In 2020 the HSE approved over half of all applications for reimbursement within 60 days of receipt of the application. This includes applications for generic medicines, biosimilar medicines, hybrid medicines and new chemical entities (orphan and non-orphan) and excludes applications for parallel imported medicines.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle'.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service