Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Rannan na nOspideil Ghearmhíochaine
Aonad 4A – Áras Dargan
An Ceantar Theas
An Bothar Mileata
Cill Mhaighneann
BÁC 8

Acute Operations
Health Service Executive
Unit 4A - The Dargan Building
Heuston South Quarter
Military Road
Kilmainham
Dublin 8.

Deputy Jennifer Murnane O'Connor TD
Dáil Éireann
Leinster House
Dublin 2

11th August 2020

PQ 20964/20 * *To ask the Minister for Health if ionafornid treatment in the rare disease progeria will be licensed here; if the State will be providing the financial burden of hospitals providing such treatment; and if he will make a statement on the matter.*

Dear Deputy Murnane O'Connor.

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question, which you submitted to the Minister for Health for response. I have examined the matter and the following outlines the position.

Response:

Lonafarnib for the management of the rare disease Huthcinson-Gilford progeria is designated an "orphan medicine" by the European Medicines Agency (EMA). Orphan medicines must undergo the EMA's centralised authorisation procedure rather than national authorisation procedures in individual EU member states. The European Commission (EC) grants a marketing authorisation (licence) based on recommendations from the EMA.

The EMA are currently assessing lonafarnib for Huthcinson-Gilford progeria under their centralised authorisation procedure. Should a marketing authorisation be granted by the EC for the use of lonafarnib for Hutchinson-Gilford progeria, the centralised marketing authorisation (licence) is valid in all EU Member States, including Ireland.

Once a valid marketing authorisation is granted, the manufacturer must then submit a pricing and reimbursement application to the HSE Corporate Pharmaceutical Unit to initiate the formal HSE assessment process for reimbursement approval. Financial and budgetary requirements are considered as part of the HSE assessment process for all new medicines.

I trust this answers your question to your satisfaction.

Helen Byrne

Helen Byrne
Assistant National Director
Acute Operations