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Friday, 31st May 2019

Deputy Mary Lou McDonald,
Dáil Eireann,
Leinster House,
Kildare Street,
Dublin 2

RE: PQ 21754/19 – To ask the Minister for Health if the HSE Leadership Team met on 14 May 2019 to consider additional information submitted by the manufacturer of the drug spinraza; and when the team will make a final decision on the reimbursement of the drug based on this information.

Dear Deputy McDonald,

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

The application for Nusinersen (Spinraza®) is currently undergoing assessment by the HSE. The statutory assessment process involves a Health Technology Assessment followed by detailed consideration by the HSE expert groups on new Drug therapies, including the Technology Review Group for Rare Diseases and the Drugs Committee.

The assessment focus is twofold and particularly centred on reviewing the evidence of the clinical effectiveness of this new drug therapy i.e. the benefits for patients undergoing clinical trials; and on the cost effectiveness of the product in view of the prices being charged for the drug, which has an estimated budget impact in excess of €20m over a five year period.

The HSE issued a notice of decision to the Pharmaceutical company in relation to Spinraza on 21st February 2019. This allows the company to make final submissions and representations – which it has now done.

The representations are being considered carefully by the HSE and an announcement regarding the final outcome of the application is expected following the HSE Leadership meeting in early June 2019.

I trust the above information is of assistance to you.

Yours sincerely,

John Hennessy

John Hennessy
National Director
Acute Strategy & Planning