\* To ask the Minister for Health when Spinraza will be made available through the HSE; and if he will make a statement on the matter.

- Brendan Smith T.D.

**REPLY**

The Health Service Executive has statutory responsibility for decisions on pricing and reimbursement of medicines, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013.

The Act specifies the criteria to be applied in the making of reimbursement decisions which include the clinical and cost effectiveness of the product, the opportunity cost and the impact on resources that are available to the HSE.

I am advised by the HSE that an application for the reimbursement of Nusinersen (Spinraza) was considered by HSE Leadership at its meeting on 12 February 2019.

Following detailed consideration of the application, the HSE Leadership made the decision that it was unable to recommend reimbursement of Spinraza and concluded that the evidence for clinical effectiveness is still quite limited and that the current price proposed by the manufacturer was not a cost-effective use of resources.

The HSE has written to the company involved and informed them of the proposal to refuse reimbursement at the current price offering. Under the requirements of the Health (Pricing and Supply of Medical Goods) Act 2013 the company now has 28 days to respond or make representations to the HSE’s proposed decision.

The HSE remains open to considering any new evidence or information which emerges regarding the clinical effectiveness or price of this medicine.