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Monday, 11th March 2019

Deputy Lisa Chambers,
Dáil Eireann,
Leinster House,
Kildare Street,
Dublin 2

RE: PQ Ref: 9979/19 – To ask the Minister for Health if the HSE is looking for a biosimilar drug to treat SMA instead of reimbursing Spinraza; and if he will make a statement on the matter.

PQ Ref: 10112/19 – To ask the Minister for Health the detail of the recommendation the Rare Disease Technical Review Committee gave on Spinraza, that is, to reimburse the drug; and if he will make a statement on the matter.

RE: PQ Ref: 10113/19 – To ask the Minister for Health the detail of the recommendation the HSE Drugs Group gave on Spinraza to reimburse the drug; and if he will make a statement on the matter.

RE: PQ Ref: 10114/19 – To ask the Minister for Health the detail of the recommendation the HSE Leadership Team gave on Spinraza to reimburse the drug; and if he will make a statement on the matter.

Dear Deputy Chambers,

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

At the outset, I wish to advise that there is no biosimilar medicine available to treat SMA.

The various reports on Nusinersen (Spinraza) were considered in detail at the February meeting of the HSE's Leadership team, taking into account the evidence of the clinical trials and the report on cost effectiveness at the price currently quoted by the Pharmaceutical company, which has an estimated budget impact in excess of €20m over a five year period.

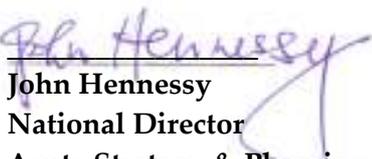
The HSE has written to the company involved (on 21st February 2019) informing them of the proposal to refuse reimbursement at the current commercial price offering. The formal notice of intention provides the company with a 28 day period to respond or provide further information – which will then be considered by the HSE in advance of making final decisions on the application for reimbursement. At this stage, it is not possible to provide you with the recommendations of the individual groups as requested until such time as the assessment process is complete.

The HSE Leadership team is keen to acknowledge the need to provide all possible support to this very vulnerable group of patients and those who care for them, but also has to have regard to the opportunity cost this would represent at the current price offering. The HSE is of course open to considering any new evidence or information regarding either the clinical effectiveness or the price offering for this medicine.

It is important to note that the HSE has approved 15 new medicines and 3 new uses of existing medicines in 2019. Assessment of the clinical evidence, cost effectiveness and budget impacts of all of those medicines was carried out in advance of approval as per the statutory responsibilities placed on the HSE under the Health (Pricing and Supply of Medical Goods) Act 2013. Those medicines were considered and assessed thorough the same processes as Nusinersen. 11 of those medicines/new uses are Orphan medicines and /or are used for Rare Diseases.

I trust the above addresses your query but please do not hesitate to contact me if you have any further queries.

Yours sincerely,


John Hennessy
National Director
Acute Strategy & Planning