



26 October 2018

Mr Colm Murphy  
Meetings Administrator  
South Dublin County Council  
County Hall  
Tallaght  
Dublin 24

Dear Mr. Murphy

Thank you for your correspondences concerning the Motions Agreed at the Meeting of South Dublin County Council held on 08 October 2018 (M2/1018 & M19/1018)

The HSE has statutory responsibility for medicine pricing and reimbursement decisions, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. The Act specifies the criteria for decisions on the reimbursement of medicines. As Minister for Health I do not have any statutory power or function in relation to reimbursement of medicines.

For a medicine to be considered for reimbursement by the HSE, it must first have a marketing authorisation from the European Medicines Agency (EMA) or the Health Products Regulatory Authority (HPRA), before being assessed under the 2013 Act.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds, on the advice of the National Centre for Pharmacoeconomics (NCPE). The NCPE conducts health technology assessments (HTAs) for the HSE and makes recommendations on reimbursement to assist HSE decisions.

The NCPE uses a decision framework to systematically assess whether a drug is cost-effective as a health intervention. This process ensures that only treatments that are clinical and cost effective are reimbursed.

Nusinersen (Spinraza) is indicated for the treatment of 5q spinal muscular atrophy (SMA), a disorder characterised by progressive muscle atrophy and weakness.

In May 2017, the EMA granted market authorisation for nusinersen and in October 2017, the HSE received a reimbursement application for nusinersen.

In December 2017, the NCPE completed a HTA of nusinersen and did not recommend reimbursement at the price submitted. The application is being considered by the Rare Diseases Medicinal Products/Technology Review Committee and the HSE Drugs Group and is due to be considered by the HSE Leadership Team shortly, following which the final decisions will be notified.

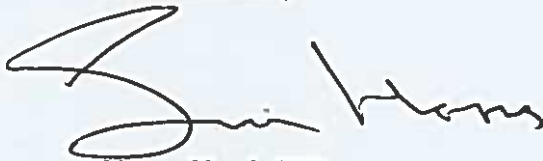
The HSE strives to reach a decision in as timely a manner as possible. However, because of the significant monies involved, it must ensure that the best price is achieved, as these commitments are often multi-million euro investments on an on-going basis. This can lead to protracted deliberative processes which are usually bound by strict confidentiality clauses at the insistence of companies.

As you will be aware, Ireland joined the Beneluxa Initiative on Pharmaceutical Policy on 22 June 2018. In July 2018 two members of the Beneluxa Initiative on Pharmaceutical Policy (Belgium and the Netherlands) completed a joint negotiation for the reimbursement of Spinraza. These negotiations began before Ireland joined the collaboration.

As a candidate country, Ireland was not notified, due to confidentiality arrangements that negotiations were occurring for the reimbursement of Spinraza and we were not party to the negotiations and proceedings that occurred.

I hope this is of assistance to you.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Simon Harris', written in a cursive style.

Simon Harris T.D.  
Minister for Health