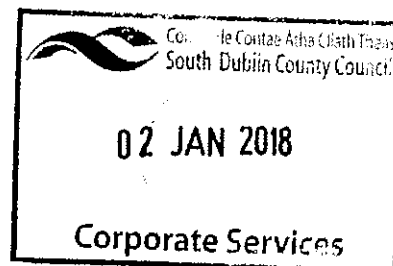




20 December 2017

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



Dear Mr Murphy

Thank you for your recent letter concerning the Motion Agreed at Meeting of South Dublin County Council held on 13th November 2017 (Ref: M07/1117).

The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines under the community drug schemes, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013.

In reaching its decision, the HSE examines all the evidence which may be relevant in its view for the decision and will take into account such expert opinions and recommendations which may have been sought by the HSE, including, for example, advice from the National Centre for Pharmacoeconomics (NCPE).

Sapropterin (Kuvan) was previously considered under the national pricing and reimbursement processes in 2009. At that time insufficient evidence was available to support the pricing and reimbursement application submitted by Merck Serono for Kuvan.

In December 2015 Merck Serono advised the HSE that the market authorisation for Kuvan was transferring to Biomarin in 2016. The HSE met with the new market authorisation holder Biomarin in May 2016 and was advised that it would be submitting a health technology assessment dossier in relation to Kuvan.

The NCPE assessment of the Biomarin dossier was completed on the 15 September 2017 and the NCPE did not recommend Kuvan for reimbursement as it was not deemed cost effective.

The HSE assessment process is ongoing and the HSE will take into account relevant expert advice when making its decision, in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

I hope this is of assistance to you.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Simon Harris', with a large, stylized initial 'S'.

Simon Harris T.D.
Minister for Health