



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte  
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Mr. Colm Murphy,  
Meetings Administrator,  
Corporate Services Department,  
South Dublin County Council,  
County Hall, Tallaght,  
Dublin 24.

29<sup>th</sup> December, 2017

**REPDR/17/04778**

**Your reference: M07/1117**

Dear Mr. Murphy,

I refer to motion "That this Council calls on the Government and the HSE to authorize the drug Kuvan for those living with Phenylketonuria (PKU) in Ireland" which was agreed at meeting of South Dublin County Council held on 13<sup>th</sup> November 2017.

I wish to advise as follows:

There are formal legal processes which govern the pricing and reimbursement of medicines.

Part 3 of Schedule 3 of the Health (Pricing and Supply of Medical Goods) Act 2013 requires the HSE to consider the following criteria prior to making any decision on reimbursement:

- (1) The health needs of the public (paragraph (a));
- (2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services (paragraph (b));
- (3) The availability and suitability of items for supply or reimbursement, or both, under Section 59 of the 1970 Act (paragraph (c));
- (4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks (paragraph (d));
- (5) The potential or actual budget impact of the item or listed item (paragraph (e));
- (6) The clinical need for the item or listed item (paragraph (f));
- (7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety (paragraph (g));
- (8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) (paragraph (h)); and
- (9) The resources available to the HSE (paragraph (i)).

In addition there are framework agreements in place with the international pharmaceutical industry which detail the steps the HSE follows in its formal reviews of pricing and reimbursement.

Kuvan® is under consideration within the processes agreed with the Pharmaceutical Industry and in line with the Statutory Requirements set out in the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE has received a pricing and reimbursement application in relation to this medicine. The HSE has

received a health technology assessment report from the National Centre for Pharmacoeconomics (NCPE) a summary of which is available on the NCPE website @ [www.ncpe.ie](http://www.ncpe.ie) .

The HSE has met the relevant company recently to discuss the report from the NCPE and to discuss commercial options. The medicine (and all relevant information including any commercially confidential offering) is expected to be considered by the HSE Drugs Group, the review group which the HSE has put in place to provide recommendations to HSE decision makers.

Decision making in relation to all financially significant investments is reserved to the National HSE Leadership Team / HSE Directorate in Q1 2018. The HSE cannot make any comment on possible outcomes from the formal process.

The HSE has noted commentary or expectation that the application being assessed involves the provision of treatment to hundreds of patients. As part of the ongoing process the HSE will carefully consider all the information provided to it. In particular, the HSE is assessing whether the budget impact estimated by the applicant company which is based on a small numbers of patients being treated (i.e. a total of 27 patients in year 5) is realistic. The HSE will also be reviewing company commercial proposals to understand fully what the impact of any proposal is on the most realistic (once fully established) estimates of the resources that would be required to reimburse this medicine.

Yours sincerely,

  
Kieran Healy  
Head of Customer Services