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Disclaimer:

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It is subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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Introduction

Epilepsy is a disorder where recurrent seizures are caused by abnormal electrical discharges from the brain. Most seizures can be controlled by one or more antiepileptic drugs (AEDs) but drug-resistant seizures may develop. The ketogenic diet was introduced prior to the introduction of these modern drugs and continues to be used, particularly for those who do not respond to drug treatment. Therefore, it was claimed that Namyang Ketonia (Korea) is the world's first and only commercially available ketogenic liquid formula for special medical purposes intended for infant and young children with epilepsy.

This technology review was conducted following a request from Food Safety and Quality Division, Ministry of Health (MOH) Malaysia, in providing technical input for them to make a decision/approval regarding a proposal to import special purpose food, Namyang Ketonia as a ketogenic diet treatment for epilepsy.

Objective/Aim

The objective of this technology review was to review evidence on the effectiveness, safety and cost-effectiveness of Namyang Ketonia as a ketogenic diet treatment for epilepsy in infant and young children.

Results and Conclusions

There was limited but good level of retrievable evidence on the effectiveness of Namyang Ketonia as a ketogenic diet treatment for epilepsy in infant and young children. All studies seemed to show more than 50% reduction in seizure compared to their comparative controls at three months, and this response was maintained for up to a year. However, the evidence obtained was not properly designed RCTs because studies included are limited by small sample sizes and of short duration. Some studies did not specify the randomisation process, and none were blinded. Outcome measures relating to seizure control such as seizure reduction were not well-defined and specified.

There was no retrievable evidence on United States Food and Drug Administration (US FDA) approval or CE mark for this product. Some studies recorded a range of side effects, the most prevalent being gastrointestinal effects. According to the manufacturer, the price is USD [REDACTED] (RM [REDACTED]) per carton (24 packs per carton; weight 180 ml per pack).

Based on the review, research is warranted to provide high quality scientific evidence to support ketogenic diet as a treatment for epilepsy in infant and young children.

Methods

Literatures were searched through electronic databases specifically PubMed, Medline, Cochrane, Ovid, Horizon scanning databases, other websites; US FDA, MHRA and from non scientific database - Google search engine. In addition, a cross-referencing of the articles retrieved was also carried out accordingly to the topic. Relevant articles were critically appraised and evidence graded using US/Canadian Preventive Services Task Force.