

PD-115 - (21SPP-11492) - REVIEW OF MEDICAL DEVICES FOR PEDIATRIC COUGH

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Introdução e Objectivos

Cough is the most common acute symptom in childhood. Complex natural substances found in medical devices (MD) are a new category of cough remedies. MD have distinct requirements for registration and evaluation from drugs and other medicinal products, but there is an ill-defined frontier between these products. We aimed to identify and characterize MD and MD components with an explicit pediatric indication on cough currently marketed in Portugal, and their evidence base.

Metodologia

We used online Google and pharmacies searches, the National Association of Pharmacies catalog and National Authority MD database to identify and collect data on registered MD. We identified the most common MD components and searched MEDLINE and grey literature for comparative studies in pediatric cough.

Resultados

We included 26 MD. Data was incomplete across the different items. Fourteen were class IIa and 8 class I devices. The labelled younger age of use was 6 months old. Some MD recommended different doses for children and adults without an age cut-off. Most leaflets did not identify sections on adverse effects and interactions. The most frequent components were honey, *Althaea* and *Plantago major*. Nine controlled studies included showed honey was more effective than placebo in relieving nocturnal and diurnal cough and improving clinical scores. We did not find any comparative study that confirmed the efficacy of *Althaea* and *Plantago major* as a single extract for post-viral acute cough in children.

Conclusões

The use of MD for pediatric cough is hindered by the diversity of components and the limited information available. There is an urgent need to improve the evidence base on their efficacy and safety for relieving post-viral acute cough.

Palavras-chave : Medical Devices, Review, Cough, Pediatric