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A Regulator's Assessment of Consumer Risk When Evaluating a User Test for an Umbrella Brand Name in an over the Counter Medicine

Authors : A. Bhatt, C. Bassi, H. Farragher, J. Musk

Abstract : Background: All medicines placed on the EU market are legally required to be accompanied by labeling and package leaflet, which provide comprehensive information, enabling its safe and appropriate use. Mock-ups with results of assessments using a target patient group must be submitted for a marketing authorisation application. Consumers need confidence in non-prescription, OTC medicines in order to manage their minor ailments and umbrella brands assist purchasing decisions by assisting easy identification within a particular therapeutic area. A number of regulatory agencies have risk management tools and guidelines to assist in developing umbrella brands for OTC medicines, however assessment and decision making is subjective and inconsistent. This study presents an evaluation in the UK following the US FDA warning concerning methaemoglobinaemia following 21 reported cases (11 children under 2 years) caused by OTC oral analgesics containing benzocaine. METHODS: A standard face to face, 25 structured task based user interview testing methodology using a standard questionnaire and rating scale in consumers aged 15-91 years, was conducted independently between June and October 2015 in their homes. Whether individuals could discriminate between the labelling, safety information and warnings on cartons and PILs between 3 different OTC medicines packs with the same umbrella name was evaluated. Each pack was presented with differing information hierarchy using, different coloured cartons, containing the 3 different active ingredients, benzocaine (oromucosal spray) and two lozenges containing 2, 4, dichlorobenzyl alcohol, amylmetacresol and hexylresorcinol respectively (for the symptomatic relief of sore throat pain). The test was designed to determine whether warnings on the carton and leaflet were prominent, accessible to alert users that one product contained benzocaine, risk of methaemoglobinaemia, and refer to the leaflet for the signs of the condition and what to do should this occur. Results: Two consumers did not locate the warnings on the side of the pack, eventually found them on the back and two suggestions to further improve accessibility of the methaemoglobinaemia warning. Using a gold pack design for the oromucosal spray, all consumers could differentiate between the 3 drugs, minimum age particulars, pharmaceutical form and the risk factor methaemoglobinaemia. The warnings for benzocaine were deemed to be clear or very clear; appearance of the 3 packs were either very well differentiated or quite well differentiated. The PIL test passed on all criteria. All consumers could use the product correctly, identify risk factors ensuring the critical information necessary for the safe use was legible and easily accessible so that confusion and errors were minimised. Conclusion: Patients with known methaemoglobinaemia are likely to be vigilant in checking for benzocaine containing products, despite similar umbrella brand names across a range of active ingredients. Despite these findings, the package design and spray format were not deemed to be sufficient to mitigate potential safety risks associated with differences in target populations and contraindications when submitted to the Regulatory Agency. Although risk management tools are increasingly being used by agencies to assist in providing objective assurance of package safety, further transparency, reduction in subjectivity and proportionate risk should be demonstrated.

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