

Similar is the problem with oral combinations such as amoxicillin-clavulanic acid available in India. To overcome this problem, we suggest following solutions: (i) It will be preferable to mention only the amount of active drug in the injection vial/oral preparation prominently and the contents could give the details. For example, vial of a combination of cefoperazone (500 mg)-sulbactam (500 mg), currently labeled as 1 g, could be labeled as 500 mg; (ii) The physicians and nurses should take care while prescribing / administering and should clearly mention / administer the dose of the active compound.

We will like to alert the pediatricians about this error so that they can identify this and take corrective actions.

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How Baby Friendly are the Baby Products?

Recently there has been controversy about baby products of a famous Multinational company. A child in Amaravati, Maharashtra, developed blisters after application of its baby oil. Oil application was stopped and the blisters subsided. Subsequently a complaint was lodged with the FDA (Food and Drug Administration), Maharashtra. It was discovered that a total of thirty-nine complaints were filed with this company from January 2004 to February 2005 for skin reactions following use of baby oil, but the company did not initiate any action.

In this company's baby oil, liquid paraffin amounts to 99.78%, rest being tocopheryl

acetate 0.1%, vitamin A and D3 mixture 0.1%, perfume 0.015%(1). Liquid paraffin is a documented emollient to be applied for rashes, itching and dry skin. It is not massage, oil. But the label on this oil reads "It is ideal massage oil for your baby. Daily massage has clinically shown to benefit baby's growth and development". For baby massage vegetable oils have been shown to be superior to products containing mineral oil(2). Vegetable oils significantly improve growth as well as blood flow as compared to the mineral oil. Vegetable oils are well absorbed from the skin. Further, mineral oils may clog the pores of the skin and can cause allergic reactions. The label on baby oil also claims it is vitamin D enriched whereas its vitamin D content is only 0.1% together with vitamin A and the claim of beneficial effect accruing from such low concentrations could not be substantiated by the company.

As regards baby shampoo of this company FDA Maharashtra has said that “this product is a misnomer to be a baby product; company’s claims regarding benefits accruing from its use are substantiated by data obtained from clinical trials conducted on adult citizens in USA”. FDA Maharashtra has also cited various discrepancies in claims made by the company with regards to this company’s baby milk soap, baby lotion, baby milk lotion, baby hair oil *etc.*

In its order FDA had asked this company to drop the word “baby” from its products meant for infants. FDA had also served a notice on the company asking it to provide substantial clinical evidence to prove that its Baby Oil brand is safe for use by children, as claimed in the product’s label. In China also, Taipei City Government’s health authorities have been instructed to conduct examinations of the company’s baby products. But this is not the only company selling such products. In chaotic and unregulated Indian market there is a plethora of baby products with questionable claims and ingredients, some of them by reputed companies. FDA has also initiated action against such companies(3).

This issue needs a thorough discussion and raises some questions. Scientifically, is there a need for specialized oil, lotion, shampoo, powder and soaps for the use of newborns and infants? If yes then what are the criteria and guidelines for their composition and suitability to babies? If no, then why these products are in the market? Items sold as baby products are expensive as compared to the traditional products. Aggressive promotion in the print and electronic media have resulted in mothers and young parents buying these products at fancy prices believing that these products have special attributes that help growth, development and health of the babies.

Under the Drug and Cosmetics Act, the

regulation of manufacture, sale and distribution of Drugs is the concern of the State authorities while the Central Authority (Drug Controller of India) is responsible for approval of new drugs, clinical trials in the country and laying down the standards for Drugs, *etc.* So the state and central bodies have to work in tandem to address such issues. Consumer activists should also take up the issue of awakening the community from the ill effects/hazards due to unnecessary use of such products. TV / print advertisements should be modified or banned as they are the modes of aggressive sale promotion and parental misguidance.

IAP is expected to perform its role as a watchdog to protect the health and ensure the rights of a child consumer. IAP should alert itself to this important matter and issue guidelines on this matter to pediatricians as well as related Government bodies.

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