5PSQ-094 USE OF EXCIPIENTS IN ORAL LIQUID COMMERCIAL MEDICINES IN A CHILDREN'S HOSPITAL

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Background Oral liquid medicines, such as solutions and suspensions, are commonly given to young children, because they are easy to swallow and allow weight-based dosage. The development of oral medicines for paediatric patients often requires age-appropriate formulations which can be more complex and may involve a broader range of excipients than adult dosage forms.

Purpose Identify excipients having a potential risk of safety concerns in the paediatric population of commercial oral liquid medicines of our hospital formulary.

Material and methods All oral liquid medicines included in the hospital's drug formulary were reviewed, using components information from the summary product characteristics obtained from the Spanish Medicament Agency (AEMPS[1]), and compared with the oral excipients from the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.[2]

Results We reviewed 96 SPC oral liquid medicines, 16 oral drops and 80 suspensions or solutions, only 12 of which were non-indicated excipients-free.

Bold excipients contraindicated in neonates/children less than 6 years. Italic: contraindicated in patients with metabolic disorders.[3]

Abstract 5PSQ-094 Table 1

Excipient	Percentage (%)
Aspartame	4
Azo colouring agents	4
Benzoic acid (E210) and benzoates	25
Benzyl alcohol	3
Cyclodextrins	1
Ethanol	19
Fructose	5
Glucose	6
Glycerol (E422)	27
Gluten	2
Sulphites including metabisulphites	1
Sucrose	31
Soya oil/hydrogenated soya oil	3
Sorbitol (E420)	21
Propylene glycol (E1520) and esters of propylene glycol	25
Phenylalanine	1
Parahydroxybenzoates and their esters	33
Mannitol (E421)	5
Maltitol (E965)	3
Macrogolglycerol ricinoleate	1
None	13

Conclusion A high percentage (87%) of liquid medicines in our formulary commonly used to treat children contain potentially harmful excipients. So, specific criteria have to be implemented in the drug procurement process. The use of excipients in paediatric medicines is driven by functional requirements and should be justified through a risk-based assessment, considering, among others, the paediatric age group, frequency of dosing and duration of treatment and excipient concentration. Clinicians should be aware of this in prescribing appropriate treatment in this population. When a commercial medicine contains an excipient that can cause problems in paediatrics, compounding may be an appropriated solution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-095 ABSTRACT WITHDRAWN