5PSQ-124. EXCEEDING SAFE EXCIPIENT LIMITS IN NEONATOLOGY UNIT MEDICATIONS: A CALL FOR SAFER PHARMACEUTICAL ALTERNATIVES

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BACKGROUND

Excipients in drug formulations are often considered harmless, but in neonates, their immature metabolism can lead to accumulation, potentially exceeding the acceptable daily intake (ADI) and causing harm.

OBJECTIVE

Analyse the presence of harmful excipients (HE) in pharmaceutical specialties (PS) used in neonatology unit (NICU) and propose safer alternatives for those that exceed ADI.

MATERIAL AND METHODS

Descriptive observational study of the PS consumed in the NICU over last 6 months.

Harmful excipients

- Benzoates
- Benzyl alcohol
- Benzalkonium chloride
- Ethanol
- Polysorbate 80
- Propylenglycol
- Parabens
- Sorbitol

Reviewed qualitative and quantitative composition.

Calculation ADI based on the extrapolation of excipient exposure from the maximum usual daily drug doses.

Safer alternative PSs were sought if exceeded ADI.

RESULTS

Analyse 76 PS: 75 Summary of product characteristics were available.

Routes of administration	Number of PS
Parenteral	44
Oral	18
Topical	7
Ocular	5
Inhalation	1
Endotracheal	1

19 PSs (25%) contained at least one HE:

6 ethanol
5 propylenglycol
5 parabens
3 benzyl alcohol
3 benzoates
2 benzalkonium chloride
2 sorbitol a
none PSs polysorbate 80

13 (17%) contained HEs quantities that exceeded ADI:

5PSs replaced with commercial alternatives

2 PSs were replaced by pharmaceutical compounding

6 PSs no alternative was available

CONCLUSION AND RELEVANCE

1. Neonates are frequently exposed to HEs. Some prescribed drugs exceeding ADI, and in some cases, these drugs could be administered simultaneously. Detecting the presence of HEs in medications used in NICU is critical for selecting the safer options.
2. Composition in HE was missing in some summary of product characteristics, despite being required by the EMA, and in some instances, no safer alternatives were available.
3. Development of paediatric medicines with appropriate excipients is necessary.

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