EVALUATION AND ANALYSIS OF HUMAN HEALTH HAZARDS OF RAW MATERIALS USED FOR COMPOUNDING IN THE HOSPITAL PHARMACY DEPARTMENT

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BACKGROUND AND IMPORTANCE

The 1272/2008 CLP-Regulation aims to ensure a high level of protection of human health and environment, harmonising the classification, labeling and packaging for dangerous substances and mixtures. This information is presented in the raw material (RM) safety data sheet (SDS).

In our pharmacy-department (PD), RM are mainly acquired from two suppliers and the hazards to human health (HHH) are evaluated to ensure professionals´s safety.

AIM AND OBJECTIVES

Evaluate the SDS from the two suppliers of all RM used for compounding, describe HHH, analyze any discrepancies that may exist and make a decision.

MATERIAL AND METHODS

- **A descriptive observational study was carried out, including all RM.**
- **The SDS from both suppliers were evaluated.**

The variables collected were:

- **CAS-number,**
- **SDS revision date,**
- **CLP-Clasification**
- **HHH.**

The following HHH-categories were defined:

- **Category 1: reproductive-toxicity/lactation (H360, H361, H362).**
- **Category 2: mutagenicity/carcinogenicity (H340, H341, H350, H351).**
- **Category 3: organ-toxicity (H370, H371, H372, H373).**
- **Category 4: Eye-damage/irritation (H318, H319, H314).**
- **Category 5: Skin/dermal-toxicity (H310, H311, H312, H315, H317).**
- **Category-6: inhaled-toxicity/sensitisation/respiratory irritation (H330, H304, H331, H332, H334, H335).**

Oral toxicity or narcosis hazard was excluded from the analysis.

RESULTS

113 SDS were evaluated of a total of 59 RM
58 RM were classified under CLP-Regulation by at least one supplier.
37/58 (63,8%) presented any HHH.

34/37 (91,9%) had SDS from both suppliers, founding discrepancies in 13 RM (38,2%):

- **2/13 (15,4%) were hazardous by only one supplier (erythromycin and yellowish-eosin).**
- **2/13 (15,4%) had completely different HHH (enalapril and pyrazinamide).**
- **9/13 (69,2%) had more HHH assigned by one supplier.**

Of these 34 RM, the discrepancies between suppliers within the HHH-category were:

- **Category 1: 4/34 (11,7%): triamcinolone acetonide, spironolactone, captopril and erythromycin (only had HHH by one supplier).**
- **Category 2: 3/34 (8,8%): anise essence, spironolactone and metronidazole. Only metronidazole had HHH by both suppliers.**
- **Category 3: 3/34 (8,8%): enalapril, metronidazole and spironolactone. Only spironolactone had HHH by both suppliers.**
- **Category 4: 6/34 (17,6%): borax, yellowish-eosin, omeprazole, captopril, isoniazid and enalapril (only had HHH by both supplier).**
- **Category 5: 6/34 (17,6%): captopril, anise-essence, isoniazid, omeprazole, pyrazinamide and spironolactone (only had HHH by one supplier).**
- **Category 6: 5/34 (14%): omeprazole, pyrazinamide, erythromycin, spironolactone and isoniazid. Omeprazole and pyrazinamide had HHH by both suppliers.**

CONCLUSION AND RELEVANCE

More than half of RM used in compounding in our PD have any HHH (highlighting the percentage of discrepancies found depending on the supplier reviewed). Thus, it is worth requesting SDS from all suppliers, carrying out an evaluation and analysis by the hospital pharmacist. In case of discrepancies, we have decided to choose the most restrictive to ensure the compounding professionals´s safety.

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