

PRESCRIBED ANTINEOPLASTIC AGENTS IN PAEDIATRIC PATIENTS

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BACKGROUND

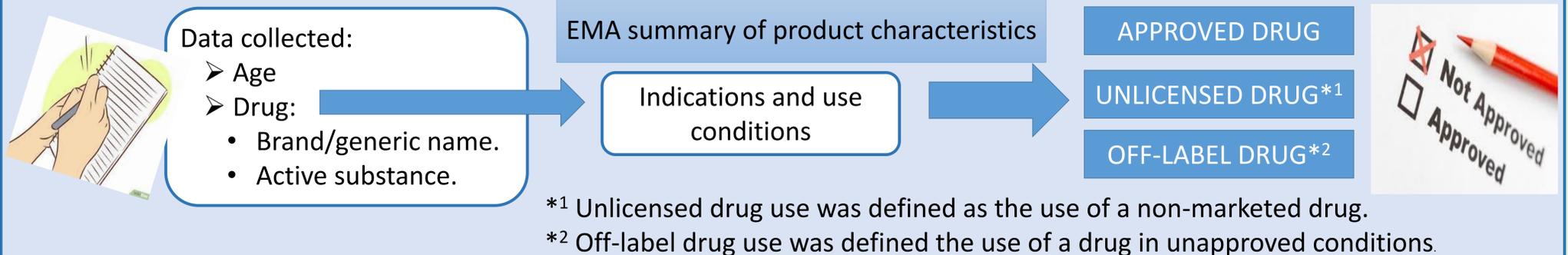
Many medicines prescribed for children have not been formally studied. Therefore, most of them are **not labeled to be used in paediatric patients**. The Regulation (EC) No-1901/2006 on medicinal products for paediatric use sets up several requirements, rewards and incentives to promote medicinal products being researched, developed and authorized covering the therapeutic needs of children.

PURPOSE

To **evaluate the prescription profile of antineoplastic agents in paediatric patients** in two relevant hospitals in Paediatrics that belong to a Regional Health Service.

MATERIALS AND METHODS

Descriptive study of antineoplastic drug prescription in paediatric patients in Oncology and Hematology Departments during 2017.



RESULTS

A total of 220 children were included (average age: 7.77 years).

647 prescriptions were evaluated.

52 different active substances (AS)



APPROVED DRUGS

OFF-LABEL DRUGS

25 different AS

Most commonly prescribed were:

- Vincristine (12.52%).
- Cyclophosphamide (8.81%).
- Cytarabine (8.50%).
- Methotrexate (8.35%).
- Etoposide (7.11%).

68.32%

18.70%

12.98%

UNLICENSED DRUGS

17 different AS

Most commonly prescribed were:

- Carboplatin (3.71%).
- Bevacizumab (2.78%).
- Ifosfamide (2.32%).
- Fludarabine (2.16%).
- Dacarbazine (1.85%).

12 different AS

Most commonly prescribed were:

- Mercaptopurine oral solution (3.71%).
- Dactinomycin (2.63%).
- Pegaspargase (2.16%).
- Asparaginase (1.70%).
- Alemtuzumab (0.46%).

- 181 children received at least one approved drug, 73 at least one unlicensed drugs and 95 at least one off-label drug.

- Unlicensed and off-label drug use in younger children was higher: 51.24% of 0-4 year old children received at least one unlicensed or off-label drug against, 46.98% of 5-11 year old children and 45.57% of 12-17 year old children.

CONCLUSIONS

Despite Regulation (EC) No-1901/2006, the results of our study show that around **two third of the children received at least one unlicensed or off-label antineoplastic agent**.

Proper clinical studies demonstrating and supporting the use of effective and safe drugs on PP are required.