

# Unlicensed and off-label drug prescription at discharge from a Swiss children's hospital

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## INTRODUCTION

For children, many drugs are used without marketing authorization ("unlicensed", e.g. imported drugs, drugs prepared by a pharmacy) or outside the terms of marketing authorization ("off-label"). In Switzerland, around half of all prescriptions for pediatric inpatients were either off-label or unlicensed<sup>1</sup>. The aim of this study was to determine the proportion of unlicensed and off-label prescriptions at discharge, which has not been investigated previously in Switzerland, and the proportion of parents informed about such a prescription.

## METHODS

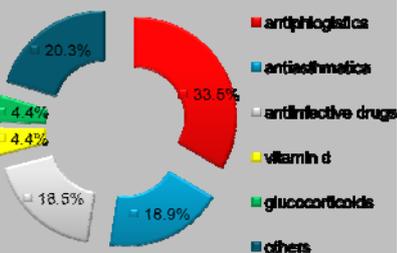
Prospective study including all discharge prescriptions of inpatients over a two-month period at the Children's Hospital of Aarau. Exclusion criteria: hospitalization for chemotherapy only, age over 18, re-entry during study period, no informed consent of parents. At discharge parents were asked to fill in a questionnaire about the information they got on discharge medication as well as about their satisfaction with this information. This questionnaire was available in german, french, croatian, turkish, albanian, spanish and english.

## QUESTIONNAIRE

## RESULTS

During the study period 503 children were discharged, 231 children could be included. For 140 children (61%) discharge prescriptions were written. Figure 1 shows the age of children getting an off-label prescription. A total of 227 drugs were prescribed, especially antiphlogistic/analgesic, antiasthmatic and antiinfective drugs (see fig.2). 38.5% of all prescriptions were off-label (see fig.3), regarding dosage in 51%, age in 40% and indication in 9% of all cases (see fig.4). Only 0.5% of drugs were unlicensed. An example of off-label prescription is shown in figure 5. Discharge questionnaires were returned of 103 of 140 children. Most parents (> 80%) were informed about purpose, dosage and use of the drugs for their child, and satisfied with obtained information, but only 9% of parents getting an off-label / unlicensed prescription for their child were informed about the off-label / unlicensed use.

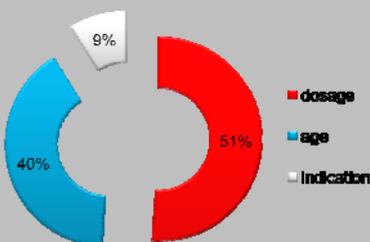
### 2 drug prescriptions



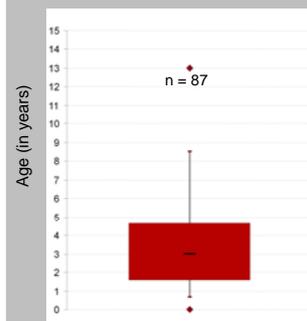
### 3 Classification prescriptions



### 4 Classification off-label prescriptions



### 1 Off-label prescription according to age



- 50% of the patients are between 1.5 and 4.7 years old
- 25% are younger than 1.5 years respectively older than 4.7 years

## CONCLUSION

There is a high percentage of drugs prescribed off-label at hospital discharge. Most drugs are well known substances and regularly prescribed for children. This emphasizes the need for an update of marketing information of older substances, or the need of a national database for drug use and dosage in children.

### 5 Antiasthmatic drugs

Ventolin® DA	Axotide® DA
• 27 x off-label in age	• 8 x off-label because of the dosage
→ There is no description of dosage <sup>1</sup> under the age of 4	→ Kompedium dosage: 2 x 100µg daily
	→ Axotide® DA dose 125µg