

# Information about use in children in Swiss drug labels is limited and needs standardisation

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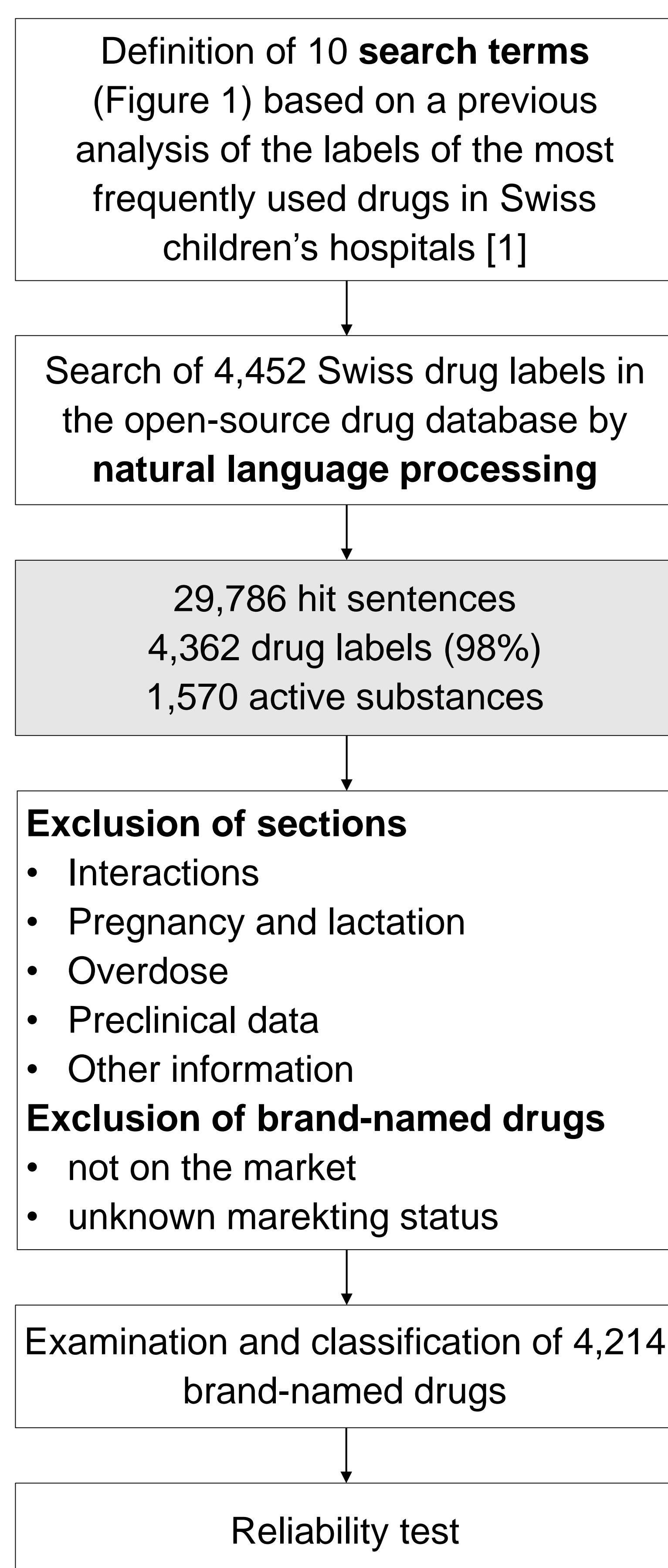
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Jugendliche  
Jugendlichen  
Kinder/Jugendliche  
Kinder  
Kindern  
Kind  
Kleinkinder  
Säuglinge  
Neugeborene  
Pädiatrie

## Introduction

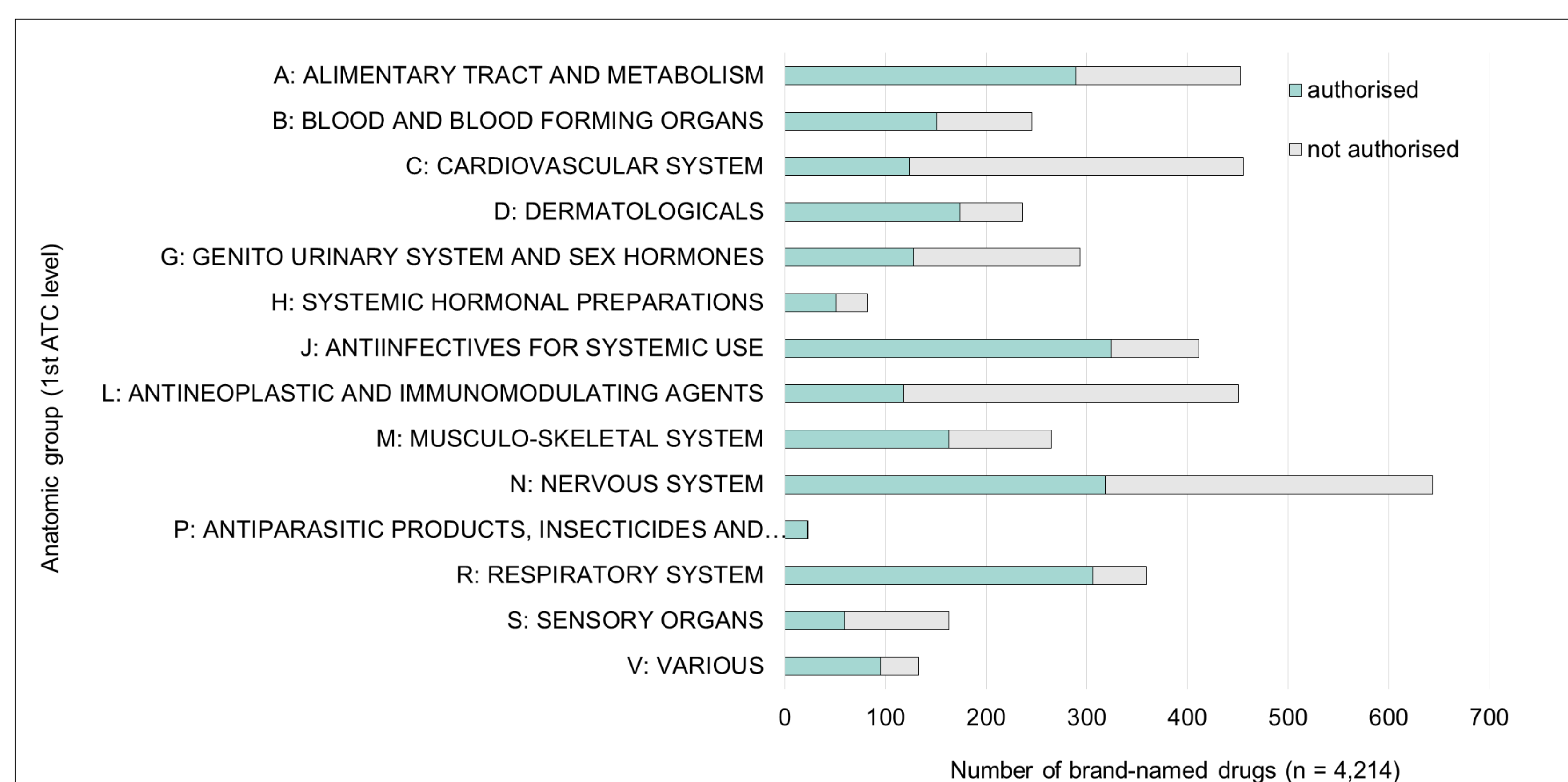
Even after the introduction of the European paediatric regulation (EC No 1901/2006), dose-finding studies and drug approval are still mostly limited to adults. As a result, a considerable proportion of drugs administered to children is not authorised for this purpose, and consequently off-label use is common in paediatric care. Studies show that in Swiss children's hospitals, about half of the prescriptions are not covered by the terms of the drugs marketing authorisation and are therefore not in accordance with the drug label. Our aim was to systematically quantify the number of drugs authorised by Swissmedic for use in children based on their current drug label. Moreover we aimed to assess and evaluate the quality of the information about the drug's use in children in Swiss drug labels.

## Methods



## Results

The retrieved sentences were most often found in the sections "Posology and method of administration" (37.4%), "Other information" (13.8%), and "Warnings and Precautions" (11.0%). Of the analysed **4,214 brand-named drugs corresponding to 1,553 substances, 2,322 (55.1%) drugs were authorised for use in children, among those 652 (15.5%) for children <2 years of age. 1892 (44.9%) drugs were not authorised for use in children** (Figure 2). As some drug labels describe multiple products with the same brand-name. One label may therefore contain different age categories for which a drug is approved, depending on the galenic formulation or dose strength, but also on indication. In only 602 (14.3%) drug labels, information on approval for children was found in the "Indications" section. 381 drug labels (9.0%) contained verbal age indications such as "children" and "adolescents" but age or age range was not clearly defined. Labels of drugs authorised for use in children also contain paediatric dosage recommendations, but those were missing in 140 (3.1%) labels. In some drug labels, no distinction is made between adults and children in the dosing recommendations.



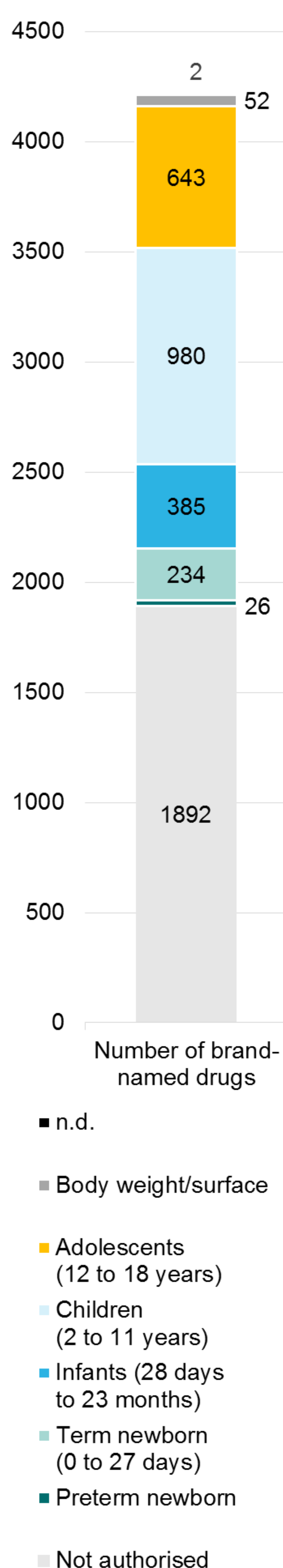
**Figure 3** Classification of authorised and not authorised brand-named drugs into the ATC index (1<sup>st</sup> ATC level). Frequently, information about children appeared in drug labels of the anatomic group "nervous system", of which almost 50% were authorised for use in children (316 vs. 326).

## Conclusion

The quality of information about drug use in children in Swiss drug labels is limited:

- 45% of brand-named drugs on the Swiss market are not authorised for use in children.
- Most drug labels contain information about children, but it refers only in 14% to an official indication.
- Even if some labels clearly indicate that use in children is authorised, a statement of the age at which the drug may be administered is missing. In addition, verbal age indications are not consistent with the official age categories classified by name and life span.
- The lack of (i) paediatric indication and (ii) a clear definition of the age in the drug label, makes it unclear for which population a drug is actually authorised or not.
- **Standardisation of information about use in children in drug labels is urgently needed in order to support health care professionals in providing the right dose for the right age of their patient.**

**Figure 1** Search terms.



**Figure 2** Number of brand-named drugs classified into different categories (n = 4,214). If different age categories were available, the youngest age was considered. n.d.; not detected.