UNLICENSED DRUGS IN PEDIATRIC PATIENTS: A SURVEY OF MANUFACTURED AND IMPORTED DRUGS IN SWISS HOSPITALS

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Introduction
Due to a lack of suited pediatric formulations, hospital pharmacies have to manufacture or import 25% to 40% of all drugs used for neonatal and pediatric patients (so-called “unlicensed drugs”).1,2 Use of such drugs may be of concern in terms of drug information (no leaflet or in another language) and continuity of care (availability in public pharmacy, reimbursement).

Objectives
One-year survey of drugs imported or manufactured for neonatal and pediatric patients in Swiss hospital pharmacies, and evaluation of the most common drug classes and substances.

Methods
Retrospective data analysis: August 2009 to July 2010; 8 representative hospital pharmacies: university: HUG Geneva, CHUV Lausanne, Inselspital Bern, Kinderspital Zurich, UMBS Basel; regional: ICHV Sion, Pic Morges, EOC Bellinzona
Included drugs: manufactured (8 hospitals) or imported (7 hospitals, UHBS not recorded) drugs primarily for neonatal or pediatric units. Excluded: drugs for enteral nutrition and total parenteral nutrition

Statistical analysis using STATA7. Comparison university/regional hospitals: Fisher’s exact test (p<0.05).

Results
Most preparations (n=499, 87%) and drugs (n=313, 90%) are manufactured resp. imported by the university hospitals. Drug classes A-D represent about 50% of the manufactured or imported substances. (Fig.1 and 2)

Production of central nervous drugs and import of new therapeutics (antineoplastic agents) are also common. Many preparations are manufactured or imported by more than 4 hospitals. (Tab.1 and 2)

Conclusion
As expected, import and manufacturing of drugs for pediatric patients are frequent in hospital pharmacies and mainly due to unsuited pediatric formulations on the Swiss market.

Most hospitals manufacture or import the same drugs. Therefore, collaboration is needed to elaborate appropriate information leaflets and to centralise manufacturing in the future.

References:
1.Di Paolo ER et al. Swiss Medical Weekly 2006;136:218-22
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Fig. 1 and 2 ATC-classification of the manufactured and imported substances

Fig. 3 Type of production (n=483 preparations; 16 unknown)

Fig. 4 Pharmaceutical forms (n=499 preparations)