Background Optimal drug therapy in children relies on availability of pediatric-specific information. European and American legislative initiatives have resulted in advancement of pediatric pharmacotherapy data. We aim to describe the quality and quantity of pediatric information in drug monographs of New Active Substances (NASs) approved by Health Canada.

Design/Methods Canadian drug monographs of NASs approved by Health Canada, from January 2007 until December 2016, were systematically reviewed for pediatric-specific information. Pediatric-specific information defined as: pediatric indication, dosing, pediatric-friendly dosage forms, and pediatric safety data.

Results Over the period of the study, Health Canada approved 281 NASs. Of all the non-biologic NASs (205, 74%), 39 (19%) were approved for use in pediatric patients. The number of drugs with pediatric approval was lowest in 2008 (1, 8%) and highest in 2016 (8, 32%), following no specific pattern. Neonates had the lowest rate of drug approvals through all pediatric age groups (4, 2%). All drugs with pediatric approval had pediatric-specific dosing information with the majority of them presenting pediatric safety data (79%). Pediatric friendly formulation was only available in 20% (8) of drugs with pediatric approval. Studies in pediatric populations were the source of pediatric information in 59% (23) of drugs with pediatric approval.

Conclusion(s) Less than 20% of the NASs approved by Health Canada for use in adults contain pediatric approval. Neonatal populations remain a therapeutic orphan, with severe lack of dosing and safety information. Safe and effective pediatric pharmacotherapy requires well-conducted pediatric research to enhance pediatric drug data. Canadian children are in need for legislative initiatives to promote pediatric drug development.

Disclosure(s) Nothing to disclose
OBJECTIVE PHARMACODYNAMIC EVALUATION OF DOXAPRAM IN PRETERM INFANTS

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Abstracts

Results Median (IQR) sufentanil central and total volume of distribution, clearance, and distribution and elimination half-life were 4.7 (4.2–5.2) L/kg and 11.8 (9.9–14.2) L/kg, 0.552 (0.415–0.671) L/h/kg, and 0.0264 (0.0260–0.0264) h and 15.7 (13.4–19.2) h, respectively.

Conclusion We observed similar sufentanil PK parameters (preliminary results) as described previously in literature. However, further studies with more patients are needed.

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P81 USE OF SYSTEMIC ANTIBIOTICS IN AUSTRIAN CHILDREN AND ADOLESCENTS: A SURVEY

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Background Several surveys that have assessed the use of antibiotic medicines for children and adolescents demonstrate significant heterogeneity in prescription patterns between different countries. The liberal use of antibacterial treatment, particularly unjustified use of broad spectrum antibiotics, is one of the main reasons for increasing rates of antibiotic resistance. We have studied antibiotics prescription frequencies in children and adolescents in Austria covering both primary and hospital care settings, in order to obtain a representative survey for our country.

Methods Prescription data for systemic antibiotics were assessed for the year 2014. For primary care, reimbursement data were obtained from Austrian health insurances. For hospital care, information on medicines dispensed to paediatric wards was obtained from hospital pharmacies. Frequencies of systemic antibiotic use were analyzed by Anatomical Therapeutic Chemical classification system, age groups, care setting, and in relation to all other medicines used. Systemic antibiotics were divided into subgroups, like broad and narrow spectrum penicillins, cephalosporins, tetracyclins, and others.

Results Systemic antibiotics comprised 24% and 21% of all medicines prescribed to children and adolescents in primary care and hospital care, respectively. The most frequent were broad spectrum antibiotics (32% and 35%) of systemic antibiotics prescribed) in both primary and hospital care settings. Macrolides and 2nd generation cephalosporins were more frequently prescribed in primary care setting, whereas β-lactam antibiotics other than cephalosporins and antibiotics, such as fluorochinolones, aminoglycosides, or linezolid were more frequently used in hospital.

Conclusions This is the first representative survey investigating the use of systemic antibiotics in children and adolescents in Austria. The study allows comparison of prescription patterns to other European countries: it reveals rather big differences to systemic antibiotics prescription in Italy, the Netherlands and Denmark, whereas prescription patterns are similar in Germany and Austria. Furthermore, this survey provides the basis to assess temporal trends in the future.

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