

Paediatric drug use with focus on off-label prescriptions in Lombardy and implications for therapeutic approaches

Authors

C. Carnovale¹, V. Conti², V. Perrone¹, S. Antoniazzi¹, M. Pozzi³, L. Merlino⁴, M. Venegoni², E. Clementi^{1,3}, S. Radice¹

¹Unit of Clinical Pharmacology, Department of Biomedical and Clinical Sciences L. Sacco, 'Luigi Sacco' University Hospital, University of Milan, 20157 Milan, Italy; ²Regional Centre for Pharmacovigilance, Lombardy, 20124 Milan, Italy; ³Scientific Institute, IRCCS Eugenio Medea, 23842 Bosisio Parini, Lecco, Italy; ⁴Operative Unit of Territorial Health Services, Lombardy, 20125 Milan, Italy

Abstract

The persistent lack of information on the paediatric use of most medicinal products is a major hindrance towards an optimal treatment of paediatric patients. It is estimated that 50–75% of medicines used in children worldwide have not been studied adequately in the paediatric population and many have not been tested at all. Even if children represent more than 20% of the European population, i.e. 100 million persons, they are often being denied proper access to new medications, or they are treated with medications that have not been subjected to scientific assessment in the same age groups. Whereas off-label drugs prescriptions represent an important therapeutic option leading to significant advances not only in the therapy but also in the knowledge of certain diseases, the use in children of dosages and therapeutic indications approved for adults often causes ineffective treatments and often lead to an increased risk of serious and unknown adverse reactions.

Several studies have documented the high prevalence of off-label use in paediatric population. No comprehensive studies, however, exist that analyse in full all prescriptions for all dispensed drugs, especially in view of the recent intervention by the European Medicine Agency to tackle this issue.

We have assessed the drug prescription pattern in the paediatric outpatient population of Lombardy, which has a reliable record of such prescriptions, focusing on off-label drug use. We analysed all dispensed outpatient prescriptions to children aged 0<18 years and the proportion of off-label drug use in 2011, using data from the regional administrative prescriptions database.

A total of 4,027,119 prescriptions were dispensed, of which 133,619 (3.3%) off-label. The Anatomical Therapeutic Chemical classes most involved in off-label prescriptions were antibiotics for systemic use (33,629), alimentary tract and metabolism (31,739) and respiratory tract (31,458). The highest rate (8%) of off-label drug prescriptions was observed in the age range 0<1. The study revealed also an inappropriate prescription pattern for fluoroquinolones and drugs targeting the cardiovascular and musculoskeletal systems.

We identified inappropriate prescriptions for specific drug classes, highlighting the need of increasing pharmacological studies in the paediatric patients, and specific critical drugs/drug classes in which such studies are particularly urgent. Depending on the region inappropriate paediatric drug prescriptions may affect different drug classes, indicating the need of tailoring specific programmes of information.

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