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СУПЕРИОРЕН ВО ТЕРАПИЈА НА РЕСПИРАТОРНИ ИНФЕКЦИИ

соодветен за сите возрасти







## The best practices and risks assessment strategy for unlicensed and "off -label" use of medicines in pediatric population

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Despite many global initiatives and efforts to improve the availability of marketing authorized dosage forms appropriate for pediatric population, there is still a supportive evidence and widespread need for the implementation of the concept of unlicensed (UL) and "off-label" (OL) medicines use as a common therapeutic strategy or as the only treatment option and standard of health care for this vulnerable population. As acknowledge, prescription, compounding, dispensing and administration of UL and OL use of medicines should be regulated within the national profile of health care policy. Bearing in mind that in our country there is no formal mechanism for management of OL drug prescribing and use that could lead to their quality use, this concept continues to be an important public health issue. For this underlining reason the purpose of our survey is to present the best practices and risk assessment strategy for UL and OU of medicines in pediatric population. First of all it is of paramount importance to establish national policies governing UL and OL prescribing and use along with ethical standard since prescribing by clinicians is an area of practice that is not regulated by drug regulatory authorities. Strategies for collaboration and the shared responsibilities among prescribers, clinicians, pharmacists and regulators with regard to the OL and UL medicines use should be developed and adopted on every level of pediatric health care. The process of determining the need for UL and OL medicines for pediatric population will serve for regulation of certain uses. Responsible OL and UL prescribing also require development of explicit guidance for pediatric clinicians to assess appropriateness, to evaluate safety and efficacy of OL and UL prescribing justified by high-quality evidence as well as in the cases where adequate evidence is lacking. Moreover, monitoring system for OL and UL medicines use by indication then, active collection of safety data and systematically monitoring of pediatric patient responses to OL use will decrease and prevent risky and ineffective OL prescribing. There is a need of policy reforms to promote care giver and public interest in evidence-based OL prescribing. Another issue that has to be regulated is the potential cost associated with this concept of use of medicines in paediatric drug therapy.