



ORIGINAL ARTICLE

# Results from the 2012–2013 paediatric national survey on off-label drug use in children in Spain (OL-PED study)<sup>☆,☆☆</sup>



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## KEYWORDS

Off-label use;  
Drug use;  
Drug approval;  
Children;  
Community surveys

## Abstract

**Introduction:** Off-label drug use is a common practice in paediatrics. The aim of the present study was to estimate the knowledge of Spanish paediatricians on off-label use.

**Materials and methods:** Cross-sectional, multicentre, descriptive and national study from July 2012 to March 2013 using an on-line questionnaire on off-label use in children. An e-mail was sent to paediatricians who were members of the Spanish Association of Paediatrics (AEP) or its Regional or Paediatric Specialties Societies.

**Results:** Out of 673 responses received, 75.1% of Spanish paediatricians knew the meaning of off-label use, 61% of them prescribed medicines outside the conditions authorised in their Summary of Product Characteristics (SPC) and 47% knew of the importance of noting the off-label use in the medical record. However, just under half of paediatricians informed parents, and only 22% wrote it down in the medical record.

**Conclusions:** Most Spanish paediatricians do not meet current regulations regarding off-label use. This regulation demands: justifying the decisions when off-label use is needed, and to write down in the medical record that, at least an oral consent from the parents has been obtained. This study reveals a fact that Spanish paediatricians must change. Meanwhile, it is a priority to continue with the implementation of consensus and clinical guidelines, to obtain more data on the efficacy and safety of off-label drug use in children, and to incorporate them into the SPC. © 2013 Asociación Española de Pediatría. Published by Elsevier España, S.L. All rights reserved.

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**PALABRAS CLAVE**

Uso *off-label*;  
Uso de  
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Encuestas  
comunitarias

## Conocimiento sobre el uso de fármacos *off-label* en Pediatría. Resultados de una encuesta pediátrica nacional 2012-2013 (estudio OL-PED)

**Resumen**

**Introducción:** Un número elevado de fármacos se prescriben en niños bajo condiciones no autorizadas en ficha técnica (uso *off-label*). El objetivo principal del estudio es estimar el conocimiento sobre el uso de fármacos fuera de ficha técnica por parte de los pediatras españoles.

**Material y métodos:** Estudio transversal, multicéntrico, descriptivo, de ámbito nacional, mediante encuesta *on-line*, enviada por correo electrónico a pediatras socios de la Asociación Española de Pediatría o de sus sociedades de Especialidades y Regionales, entre julio del 2012 y marzo del 2013.

**Resultados:** Se recibieron 673 respuestas. Un 71,5% de los pediatras españoles conocen el significado del término *off-label*, el 61% afirma que prescribe fármacos con indicaciones fuera de ficha técnica y un 47% conoce que dicho uso debe quedar reflejado en la historia clínica. Sin embargo, algo menos de la mitad informa a los padres y solo el 22% lo deja anotado en la historia clínica.

**Conclusiones:** Muchos pediatras no cumplen con la normativa actual con respecto al uso de fármacos en condiciones no autorizadas en ficha técnica. Esta normativa exige: justificar las decisiones de uso *off-label* y registrar en la historia clínica que se ha obtenido el consentimiento, al menos verbal, de los padres. Se pone de manifiesto una realidad que los pediatras españoles deben cambiar. Mientras tanto, es prioritario continuar con la realización de documentos de consenso y guías de práctica clínica para ampliar la información sobre la eficacia y seguridad de los usos *off-label* en niños, y poder incorporarlos a las fichas técnicas autorizadas.

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## Introduction and objectives

In Spanish Royal Decree 1015/2009, regulating the availability of drugs in special situations, “*off-label*” medicines are defined as “drugs used in conditions other than those included in the authorised summary of product characteristics”. The use of medications in such conditions “shall be exceptional and limited to situations in which there is a lack of authorised alternative treatments for a particular patient”. In addition, “the doctor must properly justify the need to use the drug in the patient’s clinical history and must inform the patient/guardians of the possible benefits and potential risks, obtaining their written consent”.<sup>1</sup>

A large number of medications are prescribed in paediatric practice in conditions not authorised in the summary of product characteristics (SPC). The term “exceptional”, applied to *off-label* use, implies an exception to the norm, not infrequent use. The percentage varies according to the different areas of specific training in paediatrics, but it ranges between 20 and 80% of all prescriptions.<sup>2–13</sup> Despite the publications and conference papers that have analysed the use of drugs in *off-label* conditions, and despite the measures adopted by health authorities, medicines agencies, international paediatric networks, associations and societies, paediatricians’ real knowledge of the use of drugs outside the terms of the SPC is limited. The result of this is that parents are frequently not informed that their child is going to receive a medication whose use is not authorised in the SPC, and they are not informed because paediatricians

are unaware of the administrative situation of the drugs they prescribe. It is advisable to have guidelines or protocols that support the use of the drug in children with the scientific evidence available, even if the conditions of authorisation are different. This ensures that doctors act in accordance with good clinical practice.

The main objective of the OL-PED study is to estimate the current state of knowledge on *off-label* use of drugs among Spanish paediatricians and to assess the need to adopt measures to improve this situation so as to ensure better clinical practice. Secondary objectives are to estimate how well informed they are about legal liabilities arising from *off-label* use of medications and to ascertain the sources paediatricians use to obtain information on drugs.

## Materials and methods

A cross-sectional, multicentre, descriptive, national study. Source of information for the study: data collection by anonymous, voluntary, multiple-choice *on-line* survey (Table 1), sent by e-mail to paediatricians who were members of the AEP (Spanish Association of Paediatrics), as well as to those who were members of the Specialised and Regional associations federated with the AEP. The survey was designed using Google Docs® technology.

The surveys were carried out between 1 July 2012 and 31 March 2013. Inclusion criteria: possession of a medical degree, status as specialist in Paediatrics or resident in

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