

IMPACT OF THE PAEDIATRIC REGULATION ON THE ENVIRONMENT OF PAEDIATRIC MEDICINES USE: PAEDIATRIC INVESTIGATION VERSUS OFF-LABEL DRUG USE

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Background: In 2006, the European Parliament approved pediatric standards (Pediatric Regulation 1901/2006) in order to stimulate the development of pediatric clinical trials (PCT) reducing off-label drug use (ODU).

Purpose: To evaluate the variation in PCT and ODU in children over the last 6 years once this pediatric regulation was released. We also analyzed PCT type and characteristics of drugs involved in PCT or prescribed in conditions that they are not approved (off-label)

Materials and Methods:

Observational, descriptive and retrospective study in a 252 bed children's hospital

Study period from 2007 to 2012

Main outcome: N° of PCT carried out per year and ODU per year

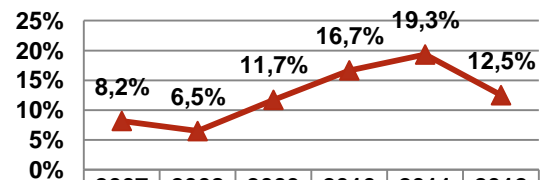
Secondary objectives: PCT design, typer of drugs used in both conditions and causes of off-label use according to the summary of product characteristics

Results:

We analyzed 87 drugs involved in PCT and 449 non investigational drugs, of which 117 (26%) were considered off-label prescriptions.

- We observed an increase in PCT carried out per year from 9 on 2007 to 23 in 2011, reaching 19.3% of total clinical trials performed in our center.
- Off-label drug use kept remained stable over the study period

- Most Frequent PCT design type was phase III non-randomized open-label (27.6%).
- Concerning involved drugs, antibiotics and antineoplastic-immunosuppressive agents were the most common drugs investigated in PCT while off-label prescriptions mainly involved hypnotic-sedatives and anticoagulants. Most cases of these off-label prescriptions were related to the lack of studies



	2007	2008	2009	2010	2011	2012
• N° ECp	9	7	15	18	23	15
— N° total EC	110	108	128	108	119	120
—▲ % ECp/ECt	8,2%	6,5%	11,7%	16,7%	19,3%	12,5%

ATC Group	Frequency Percentage	
	(N)	(%)
J	30	34,5
L	18	20,7
C	10	11,5
A	7	8,0
B	7	8,0
M	4	4,6
N	3	3,4
D	2	2,3
G	1	1,1
H	1	1,1
R	1	1,1
S	1	1,1
V	2	2,3

Conclusions:

Since January 2007 when the pediatric regulation came into force in the European Union, an increase of PCT performance has been detected in our center. However, this fact has not impacted off-label drug use which did not change mainly due to a lack of drug research in children