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Impact of regulatory measures on antipsychotics drug consumption in Castilla y León, Spain



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ABSTRACT

Objectives: Antipsychotics are currently used to treat different diseases; even some off-labelled conditions are treated with this medication. Consumption and cost of antipsychotic drugs sharply increased in Spain after second-generation drugs were marketed; several regulatory measures were adopted to curb this trend. The aim of this study was to examine the impact of these measures upon the use and cost of antipsychotics.

Study design: Study of drug use (SDU) from 1995 to 2012. Consumption and cost data were obtained from the CONCYLIA database; this database contains the retail community pharmacies sales of medicinal products reimbursed by the National Health System in Castilla y León (Spain).

Methods: Data are presented as defined daily doses per 1000 inhabitants per day (DID) and day treatment cost (DTC).

Results: First-generation antipsychotics prescriptions gradually decreased from 3.0 to 1.8 DID; meanwhile, prescriptions for second-generation antipsychotics considerably increased from 0.3 to 9.9 DID. The use of risperidone dropped after the marketing of its structural derivative paliperidone with a similar efficacy but with a substantially higher cost per day. In 2011 and thereafter, patients in Spain began to pay a part of the medications cost, but this did not decrease antipsychotics consumption. Global cost of antipsychotics only began to fall after measures were adopted to lower the price of medicines because of the economic collapse in Spain after May 2010.

Conclusion: Several health policy measures have tried to reduce antipsychotics consumption in Spain, special ways of dispensing, marketing of generic drugs and special economic measures for patients. These measures eventually failed to avoid the increase in antipsychotics use. The cost only dropped when lowering prescription drug prices took place.

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Introduction

Antipsychotic therapy is the treatment of choice for schizophrenia, but it is also an essential therapeutic option in treating other psychiatric diseases, such as bipolar disorder, autism, behavioural disorders associated with a number of different derangements characterized by cognitive impairment, as well as Gilles de la Tourette syndrome, chorea, or other types of tics and compulsive behaviours of different aetiologies.^{1,2}

In 1954, the FDA approved the use of chlorpromazine for the treatment of institutionalized patients. This led to a true revolution in the field of neuropsychopharmacology,³ given that chlorpromazine was the first of a new family of drugs, known as first-generation antipsychotic agents. However, because of their limited effectiveness on the so-called negative symptoms and issues with their safety profile, especially the concern of the occurrence of extrapyramidal side-effects, their usage was limited.⁴

There were no major therapeutic developments in the field until the 1980s, a decade in which the so-called second-generation antipsychotics were introduced for use in the clinical practice, these drugs were first marketed in Spain in 1993.¹ Following the introduction of second-generation antipsychotics in Spain, consumption of antipsychotic agents and their associated costs has been sharply increasing in Spain,⁵ from 2.90 DID in 1992 to 8.17 DID in 2006. In 2006, as much as 70% of all prescribed antipsychotic agents were second-generation antipsychotics. In the Spanish region of Castilla y León, consumption increased from 3.1 DID in 1992 to 6.7 DID in 2001 compared to 2.9 DID vs 6.1 DID in Spain as a whole, which suggests that the utilization pattern is very similar in the region of Castilla y León and Spain. The difference in the demographic characteristics of Castilla y León, compared to those of the rest of Spain, could also be associated with the slightly higher nonstandardized consumption in the region.^{5–7}

Overall, the cost of second-generation antipsychotic agent consumption is higher than that of classical antipsychotics, which contributes in explaining why in Castilla y León the spending on antipsychotics multiplied by 14 between 1990 and 2001, with the spending on second-generation

antipsychotics accounting for 80% of the total spending on antipsychotic drugs in the region in 2001.⁷

To reduce this constant increase in spending on antipsychotics, the Spanish health authorities have taken various measures, Fig. 1. From 1996, when the Spanish pharmaceutical legislation was revised and generic pharmaceutical specialties were first defined, until 2012, a large number of royal decrees and ministerial orders were passed with the aim of bringing the drug expenditure ceiling under control, with the ultimate goal being to guarantee the National Healthcare System sustainability.

The aim of the present study was to first retrospectively evaluate the evolution of both the consumption and costs arising from the use of these drugs over a lengthy period of time, i.e., from 1995 to 2012. Second, the other objective of this study was to consider the effectiveness of the measures implemented by the Spanish health authorities in order to determine which of them may be more useful in the future.

Methods

For this study of drug use, data on both the consumption and the cost of antipsychotic agents from 1995 to 2005 were collected from the ECOM database (run by the Ministry of Health, Social Welfare and Equality of Spain), in addition to data from 2006 to 2012 from the CONCYLIA database. Both sources contain information on the consumption of proprietary brands dispensed by pharmacies charged to the SNS (Spanish National Health Service). It is estimated that 99% of the Spanish population is covered by the SNS drugs benefits scheme; thus, the above sources are usually considered to be an acceptable approximation of the actual use of a drug.⁸ The total cost of antipsychotic drugs was also estimated in the present study.

The search was conducted for the period 1995–2012 and for the following active principles (ATC code—Anatomical Therapeutical Classification, N05A):⁹ phenothiazines with aliphatic side-chain (N05A A)—chlorpromazine, levomepromazine; piperazine structure phenothiazines (N05A B)—fluphenazine, perphenazine, trifluoperazine, thioproperazine; piperidine structure phenothiazines (N05A C)—periciazine,

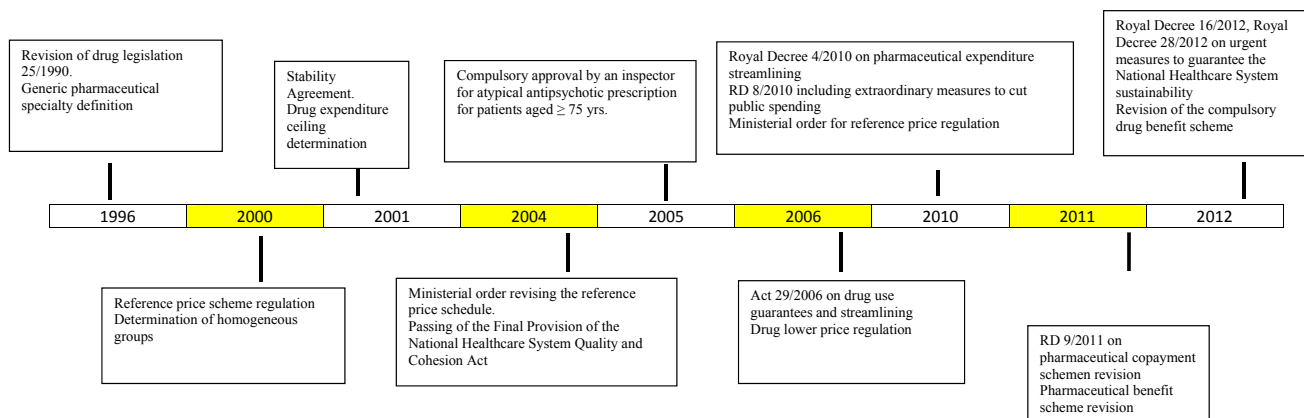


Fig. 1 – Main measures taken by the Spanish health authorities, from 1996 to 2012. Data obtained from the Official State Bulletin (BOE).

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