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Do generic firms and the Spanish public purchaser respond to consumer price differences of generics under reference pricing?

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ABSTRACT

Objectives: To assess the impact of competition on the consumer price and the average price paid by the National Health System (NHS) under reference pricing in the Spanish generic market.
Methods: Descriptive analysis of the time trend in consumer prices before and after the application of reference pricing for the eight most sold active ingredients from 1997 to 2009.
Results: The entry of a generic at a lower consumer price than that of the brand-name pharmaceutical or the first generic does not cause a voluntary reduction in the consumer price of either the brand drug or the first generic, either before or after the application of RP. Generic entry at a lower consumer price than previously existing pharmaceuticals always causes a slight reduction in the average price paid by the NHS; however, the average price paid by the NHS is always notably higher than the lowest, the difference being greater in relative terms under reference pricing.
Conclusions: The Spanish RP system results in very little consumer price competition between generic firms, price reduction thus being limited to regulatory measures. NHS purchases show little sensitivity to price differences between equivalent drugs priced at or below the reference price.

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1. Introduction

Reference pricing is a system whereby a buying agent/insurer decides on a single maximum reimbursement price for a group of equivalent medicines, and then the user/patient pays the difference if the chosen medicine is more expensive. Reference pricing (RP) systems cause an obvious and almost compulsory reduction in the consumer price of all pharmaceuticals subject to this system, to a varying degree in different countries and periods [1–3].

The literature on the impact of RP systems agrees that generics with a consumer price lower than the RP do not lower their price until the RP is lowered, even in the presence of other lower-priced generics in the market (absence of price competition below the RP) [4–6]. Zweifel and Crivelli [4] observed that RP is effective in reducing the price of brand-name drugs, but is much less effective in reducing that of generics priced below the reference price.

The results of the study conducted by Pavcnik [6] for Germany not only confirm the evidence on the reduction of drug prices already documented in previous works, but also furthermore highlight the need to differentiate the impact of RP on the consumer price from the impact of price competition (construction of the counterfactual). The study by Kanavos et al. [7] shows that, beyond the effect of RP, the number of competitors causes a slight reduction in generic prices in France and Spain, but not in Germany, the UK and Italy.

The objective of this article is to assess the impact of competition under reference pricing in the Spanish generic

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market on the consumer price and the average price paid by the National Health System (NHS), the largest public purchaser of pharmaceuticals.

To this end we conduct an empirical analysis of the time trend in the consumer price and the average price paid by the NHS for the most sold pharmaceuticals of eight active ingredients for which generic medicines exist in Spain, before and after the application of reference pricing (RP).

The Spanish pharmaceutical market is the seventh in the world in terms of sales volume. The current reference pricing system applied to generics in this market by the tax funded National Health System, which finances around 80% of medicine sales, precludes the patient from paying the difference between the consumer price and the reference price [8,9].

There are three types of prescription drugs in Spain: original brand-name drugs (which might be marketed either by the patent holder or by a licensee), copy brand-name drugs, and generics. Pharmaceutical multinational companies market their branded original products and most of them are also marketed by some Spanish companies as branded licensed products. Additionally, Spanish pharmaceutical companies market their own original branded products. The remaining marginal market is still formed by branded copy drugs, many of them priced similarly to original or licensed products, and cheaper generics.

Branded-generic medicines were introduced in the Spanish market in 1997 using the non-proprietary name (INN) plus the name of the generic producer. Primary physicians may prescribe using the brand name, even when generics are available and, in some regions they are encouraged to prescribe using the INN.

A system of "generic" reference pricing was introduced in December 2000 and remained in operation, with adjustments but without major changes, until December 2003. The number of products affected by the measure was extended in May 2002 and May 2003 with the incorporation of new groups of drugs (homogeneous sets). This system was applied to products with the same active ingredient, pharmaceutical form, dosage and number of units for which there is at least one generic. A set was created once there was at least one generic version of the respective active ingredient. For each group a reference price was calculated as the weighted average selling price of the cheapest drug accounting for at least 20% of the market. This system established the maximum price that could be reimbursed by the NHS for any version of the same drug. With this system, if the price of the prescribed medicine was higher than the reference price, the patient could choose either to replace it with another drug priced no higher than the reference price or to pay the difference between the reference price and the price of the medicine.

In January 2004 the reference pricing system was modified and since then until the final of the period analysed, as stated by Antoñanzas et al. [9], the system has been "frozen" in the sense that no other homogeneous set have been created and that no other related policies have been implemented. One modification was that the equivalence criterion for drugs affected by the system was extended. All presentations and pharmaceutical forms with the same active ingredient, whether or not they were bioequivalent, came to be grouped in the same set for the purpose of determining their reference price, on condition that there was at least one generic within the set. Thus, the reference price was calculated as the average of the three lowest costs per day of treatment for each form of administration of an active ingredient, according to its defined daily dose.

With the reference pricing system introduced in January 2004, if the price of the prescribed drug was equal to or lower than the reference price, the pharmacist must dispense the prescribed medicine; if the price of the prescribed drug was higher than the reference price and there was a generic version of it available, then the pharmacist was required to dispense the cheapest generic in the same set; and if the price of the prescribed drug was higher than the reference price but there was no generic version of it available, then the pharmacist would have to dispense the prescribed drug at the reference price. If the physician wrote the prescription using the name of the active ingredient, the pharmacist was obliged to dispense the lowest-priced generic. If there was no generic available, the pharmacist must dispense the brand pharmaceutical corresponding to the prescription concerned at the reference price.

The reference price for each homogeneous group is calculated by averaging the three current products with the lowest daily treatment costs based on DDDs (not documented in the current text). Then, of course, we may expect to see some prices above the reference price. Reference prices should be revised annually, but this has been sometimes delayed. Since 2007 generics cannot have a higher price than the reference price.

The expected officially declared outcome of the implementation of a reference pricing system such as the one in place since 2004 is a reduction in total pharmaceutical costs per capita through price reductions. Accordingly, the main hypothesis to be tested or rejected in this paper is that in the out of patent Spanish pharmaceutical market, reference pricing has encouraged price competition and has greatly and rapidly reduced generic and brand prices.

The main contribution of this article to the literature on the impact of reference pricing is to show the absence of competitive response of consumer prices of generics in the face of the entry of new lower-priced competitors, both before and after the application of RP. Furthermore, it shows the reduced sensitivity of the public purchaser to price differences between generic competitors after the application of reference pricing.

In the following section we present the method and empirical data used in this article. In the third section we present the empirical results of the analysis. These results are discussed in the fourth section. Finally, the last section contains the conclusions that can be drawn from the article.

2. Materials and methods

The working method used in this section consists of a descriptive analysis of the time trend in four price-related outcome variables: consumer price, average price paid by the NHS, number of medicines with a consumer price higher than the reference price, and ratio of the average price paid by the NHS to the lowest consumer price.

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Consumer prices and average prices paid by the NHS are measured considering independently of who pays for the medicines; that is, they include the public subsidy and the patient co-payment, when it is the case (only active population, and its families, pay 40% of the consumer price). Consumer prices and average prices paid by the NHS included VAT 4%.

These four outcome variables are observed monthly for the most sold pharmaceutical[1] of each of the eight active ingredients with the largest sales volume in the NHS in 2005 (excluding combinations of active ingredients), and for which there are generics on the market.

The time period under study is January 1997 to March 2009 for consumer price, and January 1997 to December 2005 for average price paid by the NHS.

The information sources used were the *Nomenclator Digitalis* and the pharmaceutical consumption database, both compiled by the Spanish Ministry of Health and Consumer Affairs.

The descriptive analysis was performed by observing the truth of eight hypotheses about the time trend of the outcome variables for each of the eight active ingredients selected. Each of the eight hypotheses tested is defined in terms of a regulation scenario (with or without RP), an outcome variable (one of the four defined above), an empirically observable statement about the trend of the outcome variable, and two comparison periods (before and after).

In Tables 1 and 2 we define the eight hypotheses that are tested for each of the active ingredients included in the study. Four hypotheses were defined about the trend of prices in the presence of generics in the market but in the absence of RP, and another four hypotheses were made about the price trend, again in the presence of generics but this time also in the presence of RP. In terms of choice of outcome variable, three hypotheses refer to the time trend of the consumer price, three to the average price paid by the NHS, one to the number of pharmaceuticals with a consumer price higher than the reference price and one to the ratio of the average price paid by the NHS to the lowest consumer price.

The effective before/after price variation rate calculated for each of the active ingredients in each of the hypotheses stated in Tables 1 and 2 is broken down into two components for the purpose of distinguishing the impact of price competition from the impact of regulation: the rate of compulsory variation, that which is induced by the measures adopted by the regulator; and the rate of voluntary variation (not imposed by the regulatory measures) as the firms' response to the increase in competition.

In this study, the rate of voluntary variation in the outcome variable of each hypothesis and time period was calculated by subtracting the part corresponding to the variation imposed by the regulation from the effective variation rate. To calculate the rate of compulsory variation imposed by the regulation, the initial fixing and successive revision of the RP of each of the eight active ingredients included in the study were taken into account, as were the other concurrent regulatory measures with effects on the consumer price that were adopted during the period analysed.

[1] Combination of active ingredient, pharmaceutical form, route of administration, dose per unit and number and type of units. For example, "simvastatin 20MG 28 oral tablets".

3. Results

3.1. Before the application of reference pricing

Hypothesis 1. Table 3 shows that, in the absence of RP, the rate of voluntary variation of the consumer price of brand-name drugs before and after the market entry of generics with a notably lower consumer price than the brand-name drugs was zero for all eight active ingredients. In other words, before the application of RP, the consumer price of the brand-name drugs did not fall voluntarily in any of the cases analysed, regardless of whether there were a large number of generics on the market or only very few.

Hypothesis 2. Table 4 shows that, in the absence of RP, the rate of voluntary variation of the consumer price of the first generic entering the market was zero for all eight active ingredients despite the entry of successive lower-priced generics. In other words, before the application of RP, the first generic of each active ingredient behaved exactly the same as the brand-name drugs, and its consumer price did not fall voluntarily in any of the cases analysed, regardless of whether there were a large number of generics on the market or only very few.

Hypothesis 3. Table 5 shows that, in the absence of RP, generic entry at a lower consumer price than the brand-name drugs is an effective measure for reducing the average price paid by the NHS. Comparing the average price paid by the NHS 3 months before the entry of the first generic with the average price paid before the application of RP, we observe a reduction in this average price for the six active ingredients. All the active ingredients undergo a drop in the average price paid, even after allowing for the effects of the regulatory measures: the reduction in the average price paid by the NHS, allowing for the regulatory effect, ranges from 1.65% for paroxetine to 24.08% for omeprazole.

Hypothesis 4. Table 6 shows that, in the absence of RP, with generic entry at a lower consumer price than the brand-name drugs, the average price paid by the NHS always continued to be notably higher than the lowest consumer price, both in the month of the first generic entry and 3 months before the application of RP, by which time a larger number of generics had entered the market at a lower consumer price. Three months before RP was applied, the average price paid by the NHS ranged from 21% higher than that of the cheapest product for ibuprofen to 121% higher for simvastatin. Furthermore, for four of the six active ingredients, the ratio of the price paid by the NHS and the consumer price of the cheapest pharmaceutical actually increased after the first generic entry.

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Table 1
Hypotheses on the time trend of prices in the absence of the reference pricing system.

Price variable	No.	Description of the hypothesis	Comparison period	
			Before	After
Consumer price of most sold brand	1	The entry of a generic at a lower consumer price than the brand-name drug does not reduce the consumer price of the brand-name drug.	3 months before the entry of the first generic	3 months before application of RP
Consumer price of first generic	2	The entry of new generics at a lower consumer price than the first to have entered the market does not reduce the consumer price of the latter.	Month of entry of the first generic	3 months before application of RP
Average price paid by the NHS	3	The entry of a generic at a lower price than the brand-name drug reduces the average price paid by the NHS.	3 months before the entry of the first generic	3 months before application of RP
Ratio of average price paid by the NHS to lowest consumer price	4	The entry of a generic at a lower price than the brand-name drug results in a much smaller reduction in the average price paid by the NHS than could be achieved by prescribing the medicine with the lowest consumer price.	Month of entry of the first generic	3 months before application of RP

Notes: RP = reference pricing. NHS = National Health System.

Table 2
Hypotheses on the time trend of prices under the reference pricing system.

Price variable	No.	Description of the hypothesis	Comparison period	
			Before	After
No. of presentations of a pharmaceutical	5	All presentations of a pharmaceutical with a consumer price higher than the RP reduce their consumer price to the reference level when RP is applied for the first time or revised.	3 months before application of RP or before revision of the RP	3 months after application or revision of RP
Average consumer price of the pharmaceutical	6	Successive generic entry at a lower consumer price than that of the pharmaceuticals already on the market does not reduce the consumer price of the latter.	3 months after application of RP or after revision of the RP	3 months after the entry of 3 new generics
Average price paid by the NHS	7	Successive generic entry at a lower consumer price than that of the pharmaceuticals already on the market reduces the average price paid by the NHS.	3 months after application of RP or after revision of the RP	3 months after the entry of 3 new generics
Ratio price paid by the NHS/lowest consumer price	8	Successive generic entry at a lower consumer price than that of the pharmaceuticals already on the market results in a much smaller reduction in the average price paid by the NHS than could be achieved by prescribing the medicine with the lowest consumer price.	3 months after application of RP or after revision of the RP	3 months after the entry of 3 new generics

Notes: RP = reference pricing. NHS = National Health System.

Table 3
Consumer price of the most sold brand-name product.

Active ingredient	CP before gen. (A)	CP before RP (B)	Period (C)	Rate of effective variation (%) (D)	Rate of voluntary variation (%) (E)	No. gen. (F)	Lowest CP (gen.) (G)
Amlodipine	17.58	16.16	04/03–12/06	−8.08	0.00	25	10.68
Enalapril	21.63	19.92	01/97–09/99	−7.91	0.00	2	15.36
Fluoxetine	29.91	29.44	10/98–09/99	−1.57	0.00	4	21.90
Ibuprofen	5.64	5.64	03/00–02/02	0.00	0.00	2	4.26
Omeprazole	22.38	21.00	09/99–02/02	−6.16	0.00	15	11.13
Paroxetine	33.19	33.19	07/02–10/03	0.00	0.00	2	25.00
Pravastatin	34.02	31.24	10/03–12/06	−8.17	0.00	21	18.73
Simvastatin	34.01	34.01	10/01–10/03	0.00	0.00	18	13.27
Average value	24.79	23.83		−3.99	0.00	11	15.04

Source: Authors' compilation using data from the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = consumer price 3 months before the entry of the first generic. B = consumer price 3 months before inclusion in the reference pricing system. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the consumer price of columns A and B in percent. E = variation rate between the consumer price of columns A and B in percent excluding price variations imposed by regulatory measures in force over the period. F = number of generic firms marketing the drug 3 months before inclusion in the reference pricing system. G = lowest consumer price of a generic 3 months before inclusion in the reference pricing system. CP = consumer price. Gen. = generic medicine. RP = reference pricing.

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Table 4
Consumer price of the first generic to enter the market.

Active ingredient	CP before gen. (A)	CP before RP (B)	Period (C)	Rate of effective variation (%) (D)	Rate of voluntary variation (%) (E)	No. gen. (F)	Lowest CP (gen.) (G)
Amlodipine	13.24	10.68	07/03–12/06	−19.34	0.00	8	10.68
Enalapril	17.93	17.20	04/97–09/99	−4.07	0.00	2	15.36
Fluoxetine	22.44	22.30	01/99–09/99	−0.62	0.00	4	21.90
Ibuprofen	4.23	4.55	06/00–02/02	7.57	0.00	2	4.26
Omeprazole	37.96	40.85	12/99–02/02	7.61	0.00	15	11.13
Paroxetine	26.55	26.55	10/02–10/03	0.00	0.00	2	25.00
Pravastatin	25.62	21.56	01/04–12/06	−15.85	0.00	21	18.73
Simvastatin	27.44	27.44	01/02–10/03	0.00	0.00	18	13.27
Average value	21.93	21.39		−2.44	0.00	9	15.04

Source: Authors' compilation using data from the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = consumer price of the first generic at the time of effective market entry. B = consumer price 3 months before inclusion in the reference pricing system. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the consumer price of columns A and B in percent. E = variation rate between the consumer price of columns A and B in percent excluding price variations imposed by regulatory measures in force over the period. F = number of generic firms marketing the drug 3 months before inclusion in the reference pricing system. G = lowest consumer price of a generic 3 months before inclusion in the reference pricing system. CP = consumer price. Gen. = generic medicine. RP = reference pricing.

Table 5
Average price paid by the NHS.

Active ingredient	Average NHS price before gen. (A)	Average NHS price before RP (B)	Period (C)	Rate of effective variation (%) (D)	Rate of voluntary variation (%) (E)	No. brand + gen. (F)	Lowest CP (G)
Enalapril	21.31	18.40	01/97–09/99	−13.65	−6.23	23	10.36
Fluoxetine	29.91	26.85	10/98–09/99	−10.23	−8.80	8	21.90
Ibuprofen	5.64	5.15	03/00–02/02	−8.70	−8.70	3	4.26
Omeprazole	28.15	19.64	09/99–02/02	−30.24	−24.08	36	10.21
Paroxetine	33.19	32.64	07/02–10/03	−1.65	−1.65	4	25.00
Simvastatin	33.85	29.28	10/01–10/03	−13.50	−13.50	23	13.27
Average value	25.34	21.99		−13.21	−10.49	16	15.00

Source: Authors' compilation using pharmaceutical product consumption data from the NHS and the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = average price paid by the NHS 3 months before the entry of the first generic. B = average price paid by the NHS 3 months before inclusion in the reference pricing system. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the price of columns A and B in percent. E = effective variation rate of column D minus rate of compulsory variation due to other regulatory measures in force over the period. F = number of brands (originals and copies) and generic firms marketing the drug 3 months before inclusion in the reference pricing system. G = lowest consumer price of a brand-name drug or generic 3 months before inclusion in the reference pricing system. CP = consumer price. Gen. = generic medicine.

3.2. After the application of reference pricing

Hypothesis 5. Table 7 shows that, when the RP system was applied, the consumer price of most drugs, whether they were branded or generic, fell to the reference level. For three of the eight active ingredients (enalapril, ibuprofen and paroxetine), the consumer price of all drugs fell to the reference level. For the rest of the active ingredients, only in the case of fluoxetine did none of the three drugs that existed prior to RP application fall to the reference level after the application of this system.

Hypothesis 6. Table 8 shows that, when the RP system was applied, successive generic entry at a lower consumer

Table 6
Ratio of average price paid by the NHS to lowest consumer price.

Active ingredient	Ratio first generic entry (A)	Ratio before RP (B)	Period (C)	Variation rate (%) (D)
Enalapril	1.19	1.78	04/97–09/99	49.56
Fluoxetine	1.33	1.34	01/99–09/99	0.24
Ibuprofen	1.33	1.21	06/00–02/02	−9.35
Omeprazole	2.22	1.92	12/99–02/02	−13.43
Paroxetine	1.25	1.31	10/02–10/03	4.50
Simvastatin	1.23	2.21	01/02–10/03	79.07
Average value	1.43	1.63		14.03

Source: Authors' compilation using pharmaceutical product consumption data from the NHS and the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = ratio of average price paid by the NHS to lowest consumer price at the time of the first generic entry. B = ratio of average price paid by the NHS to lowest consumer price 3 months before inclusion in the reference pricing system. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the ratio of columns A and B in percent. RP = reference pricing.

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Table 7
Number of presentations of pharmaceuticals with a consumer price higher than the reference price.

Active ingredient	Number before RP (A)	Number after RP (B)	Period (C)	Variation rate (%) (D)
Amlodipine	25	4	12/06–06/07	−84.00
Enalapril	23	0	09/99–03/00	−100.00
Fluoxetine	3	3	09/99–03/00	0.00
Ibuprofen	1	0	02/02–08/02	−100.00
Omeprazole	44	5	02/02–08/02	−88.64
Paroxetine	2	0	10/03–04/04	−100.00
Pravastatin	29	4	12/06–07/07	−86.21
Simvastatin	23	1	10/03–04/04	−95.65
Average value	18.75	2.13		−88.67

	Number before first RP revision	Number after first RP revision	Period	Variation rate (%)
Omeprazole	1	0	10/03–04/04	−100.00

Source: Authors' compilation using the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = number of presentations of pharmaceuticals with a consumer price higher than the reference price 3 months before inclusion in the reference pricing system or before its revision. B = number of pharmaceuticals with a consumer price higher than the reference price 3 months after inclusion in the reference pricing system or 3 months after the first revision of the reference price. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the ratio of columns A and B in percent. RP = reference pricing.

price than that of the pharmaceuticals already on the market did not significantly reduce the consumer price of the latter. In most of the cases observed in Table 8, after at least three new generics had entered the market following RP application or revision, the consumer price of the pharmaceuticals already on the market remained unaltered; only a slight voluntary reduction in the consumer price was observed for paroxetine (−0.69%), together with a much more notable reduction for ibuprofen (−9.48%), both occurring as of 2005.

Hypothesis 7. Table 9 shows that, when the RP system was applied, generic entry at a lower consumer price than that of the pharmaceuticals already on the market led to a slight reduction in the average price paid by the NHS beyond the price reductions imposed by other regulations.

Table 8
Average consumer price of pharmaceuticals on the market on introduction of reference pricing.

Active ingredient	Average CP at start of RP (A)	Average CP with 3 additional generics (B)	Period (C)	Rate of effective variation (%) (D)	Rate of voluntary variation (%) (E)	Lowest CP (gen.) (F)
Amlodipine	8.55	8.55	06/07–12/07	0.00	0.00	6.85
Enalapril	14.26	14.26	03/01–08/01	0.00	0.00	10.06
Fluoxetine	22.28	22.28	03/01–02/02	0.00	0.00	17.74
Omeprazole	19.45	19.45	08/02–09/03	0.00	0.00	8.69
Paroxetine	27.17	25.71	04/04–01/06	−5.39	0.00	22.79
Pravastatin	18.48	18.48	06/07–01/08	0.00	0.00	16.91
Simvastatin	14.11	13.14	04/04–06/05	−6.87	0.00	9.78
Average value	17.76	17.41		−1.75	0.00	13.26

	Average CP 1st RP revision	Average CP with 3 additional generics	Period	Variation rate (%)	Rate of voluntary variation (%)	Lowest CP (gen.)
Enalapril	12.94	12.50	08/02–06/03	−3.40	0.00	6.97
Ibuprofen	3.97	3.25	04/04–04/06	−17.73	−9.48	3.00
Omeprazole	9.19	8.48	04/04–04/06	−7.72	0.00	5.46
Paroxetine	20.33	20.19	07/07–03/08	−0.69	−0.69	14.05
Average value	11.61	11.10		−7.39	−2.54	7.37

	Average CP 2nd RP revision	Average CP with 3 additional generics	Period	Variation rate (%)	Rate of voluntary variation (%)	Lowest CP (gen.)
Enalapril	8.01	7.62	04/04–08/05	−4.87	0.00	5.60
Fluoxetine	12.94	12.08	04/04–03/05	−6.64	0.00	6.65
Average value	10.48	9.85		−5.76	0.00	6.13

Source: Authors' compilation using data from the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = arithmetic mean of the consumer price of all pharmaceuticals 3 months after introduction of the reference pricing system, or 3 months after the first or second revision of the reference price. B = arithmetic mean of the consumer price of the same pharmaceuticals as in column A 3 months after market entry of 3 new generics. C = month and year referred to in column A/month and year referred to in column B. D = rate of effective variation between the price of columns A and B in percent. E = effective variation rate of column D minus rate of compulsory variation due to other regulatory measures in force over the period. F = lowest consumer price of a generic 3 months after market entry of 3 additional generics. CP = consumer price. Gen. = generic medicine. RP = reference pricing.

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Table 9
Average price paid by the NHS between reference price revisions with at least 3 additional generics on the market.

Active ingredient	Average NHS price after RP (A)	Average NHS price with 3 additional generics (B)	Period (C)	Rate of effective variation (%) (D)	Rate of voluntary variation (%) (E)
Enalapril	14.62	14.20	03/01–08/01	−2.87	−2.87
Fluoxetine	24.43	24.34	03/01–02/02	−0.37	−0.37
Omeprazole	17.16	15.94	08/02–09/03	−7.12	−7.12
Simvastatin	13.94	12.82	04/04–06/05	−8.06	−1.28
Average value	17.54	16.83		−4.07	−2.91
	Average NHS price 1st RP revision	Average NHS price with 3 additional generics	Period	Rate of effective variation (%)	Rate of voluntary variation (%)
Enalapril	12.05	11.58	08/02–06/03	−3.90	−0.52
	Average NHS price 2nd RP revision	Average NHS price with 3 additional generics	Period	Rate of effective variation (%)	Rate of voluntary variation (%)
Enalapril	7.19	6.71	04/04–08/05	−6.65	−1.87

Source: Authors' compilation using pharmaceutical product consumption data from the NHS and the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = average price paid by the NHS 3 months after application or revision of the reference price. B = average price paid by the NHS 3 months after market entry of 3 additional generics. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the price of columns A and B in percent. E = rate of effective variation of column D minus rate of compulsory variation due to other regulatory measures in force over the period. NHS = National Health System. RP = reference pricing.

For all the active ingredients observed in Table 9, after RP application or revision and the subsequent market entry of at least three new lower-priced generics, the average price paid by the NHS fell by between 7.12% for omeprazole and 0.37% for fluoxetine.

Hypothesis 8. Table 10 shows that, when the RP system was applied, with the entry of generics at a lower price than that of the pharmaceuticals already on the market, the average price paid by the NHS always continued to be notably higher than the consumer price of the cheapest product, both after the initial application of reference pricing and after its subsequent revision, by which time a larger number of generics had entered the market at a lower consumer price. Three months after the application of the RP system, the average price paid by the NHS ranged from 18% higher than that of the cheapest product for simvastatin to 69% higher for omeprazole. When three additional generics had entered, the ratio of the average price paid by the NHS to the cheapest consumer price increased with respect to the situation prior to RP, except in the case of fluoxetine.

4. Discussion

The results presented in this article show that the consumer price of generic medicines in Spain under the reference pricing system hardly registered any reduction due to price competition, and that it did not fall as rapidly as in countries that do not apply reference pricing.

The descriptive results given here indicate a very minor role for price competition at the consumer price level; in most of the cases observed no reductions occurred in the consumer price except those resulting from the impositions made by the regulation, despite the fact that this consumer price was notably higher than the lowest consumer price for the same type of drug. This manifest insensitivity of the consumer price of both brand-name pharmaceuticals and generics to the potential effects that could be derived from price competition in the presence of lower-priced generic substitutes is found regardless of whether the reference pricing system is in force or not. With the exception of the case of ibuprofen, no significant reductions in the consumer price were observed that were not a direct result of the application of the RP system or other concurrent regulatory measures such as reductions in markups or compulsory ex-factory price reductions.

In the absence of the system of reference pricing, this manifest insensitivity of the consumer price to major price differences has no other explanation than the lack of sensitivity of the public purchaser, the NHS, to differences in drug prices. In a context of low effective co-payment and a public purchaser with a low price elasticity, there is little incentive for competition to manifest itself through consumer price reductions, although this is no impediment for this competition to manifest itself at the level of ex-factory prices in the form of discounts offered by manufacturers to pharmacies [10].

The price elasticity of demand seems to continue to be low after the application of the RP system: once the consumer price had fallen to the reference level, only one of the eight active ingredients analysed showed any evidence of voluntary reductions in the consumer price beyond those imposed by the regulator (Table 8).

In this regard, far from encouraging effective price competition at the consumer price level by means of policies that heighten the sensitivity of both public purchaser and patients to the substantial consumer price differences between the (near) substitute medicines that appear with generic entry, in Spain the chosen line of action has been to give even greater importance to price regulation through the RP system. As a result, the application of RP and other concurrent price regulation measures has been practically the only effective and successful measure to yield a notable reduction in the consumer price following generic entry.

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Table 10
Ratio of average price paid by the NHS to lowest consumer price between reference price revisions with at least 3 additional generics on the market.

Active ingredient	Ratio after RP (A)	Ratio with 3 additional generics (B)	Period (C)	Variation rate (%) (D)
Enalapril	1.43	1.46	03/01–08/01	2.02
Fluoxetine	1.37	1.37	03/01–02/02	0.00
Omeprazole	1.69	1.83	08/02–09/03	8.55
Simvastatin	1.18	1.31	04/04–06/05	11.14
Average value	1.42	1.49		5.22
	Ratio after 1st RP revision	Ratio with 3 additional generics	Period	Variation rate (%)
Enalapril	1.50	1.66	08/02–06/03	10.67
	Ratio after 2nd RP revision	Ratio with 3 additional generics	Period	Variation rate (%)
Enalapril	1.06	1.20	04/04–08/05	13.19

Source: Authors' compilation using pharmaceutical product consumption data from the NHS and the *Nomenclator Digitalis* published by the Spanish Ministry of Health and Consumer Affairs.
Notes: A = ratio of average price paid by the NHS to lowest consumer price 3 months after application or revision of the reference price. B = ratio of average price paid by the NHS to lowest consumer price 3 months after entry of 3 additional generics. C = month and year referred to in column A/month and year referred to in column B. D = variation rate between the ratio of columns A and B in percent. RP = reference pricing.

The RP system adopted in Spain, excluding from public funding those medicines with a consumer price higher than the RP as of 2004, acts in practice as a system of exclusion from or inclusion within public funding based on the RP level, but with a low price elasticity when the consumer price is lower than this RP. As is to be expected, most medicines with a consumer price higher than the RP reduce their consumer price to the reference level when the system is applied for the first time or revised, and maintain it unchanged until the next RP revision, the potential price competition provided by generics with a consumer price lower than the RP thus having almost no effect.

Although the sensitivity of both patients and NHS to consumer price differences between equivalent medicines is presumed to have been low before the application of the RP system, the average price paid by the NHS fell notably as of generic entry. Reductions in the average price paid by the NHS, beyond those reductions imposed on the consumer price by the regulator, are a result of the shift in prescription and dispensing towards presentations of the same pharmaceutical with a lower consumer price. This appears to indicate a certain effective impact of some measures aimed at raising the sensitivity of patients (co-payment), prescribers (information systems, incentive policies, prescription in terms of active ingredient, etc.) and pharmacies (differential markups, compulsory substitution). After the introduction of RP, this reduction in the average price paid by the NHS, on top of the reductions imposed by the price regulation as such, continued to exist but to a lesser degree; it was the RP system itself, as the purchasing policy of the NHS, that constituted the main tool for reducing the consumer price and hence public expenditure, at the cost of a greater increase in prescriptions of lower-priced generics.

Nevertheless, before and even after RP application, the average price paid by the NHS continued to be notably higher than the lowest consumer price observed at any given moment in time. In this way, the ratio of the average price paid by the NHS to the consumer price of the cheapest medicine did not fall after the application of the RP system. In other words, despite the evidence of the savings generated for the NHS by generics, the lowest consumer price was still notably lower than the average price paid by the NHS, indicating an NHS drug purchasing policy with substantial room for improvement.

The empirical analysis presented in this article is not without its limitations. The information used refers to only a limited number of active ingredients, and the most sold presentation of each of them, although these active ingredients are the most sold of those that have generics. Furthermore, information on the average price paid by the NHS was only available up to 2005.

5. Conclusions

In Spain from 1997 to 2009, and both before and after the application of reference pricing, generic entry at a lower consumer price than the brand-name product or other generics already on the market caused no competitive reaction in the price of the latter, all of them maintaining their price as initially authorized. The consumer price only fell when the reference price was revised, and it was observed that practically all medicine prices higher than the reference level came down to this level, while those below it remained unchanged.

When there were generics at a variety of different prices below that of the brand-name drug, both before and after the introduction of the reference pricing system, part of the NHS consumption shifted towards the lower-priced generics. However, the average price paid by the public purchaser was still high in relative terms in comparison with the consumer price of the cheapest equivalent medicine when reference pricing was applied.

Generic entry implies the existence of potential competition in each active ingredient for which regulatory entry barriers (patents) are no longer in force. The pharmaceutical financing system adopted by the Spanish NHS gives little weight to price competition at the consumer price level, and is based on obtaining compulsory consumer price reductions via the RP system itself and other concurrent price regulation measures. This NHS purchasing policy has led to an increase in price regulation, precisely when market entry barriers due to regulation cease to exist, to the

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detriment of measures aimed at increasing the sensitivity of consumers and prescribers to price differences at the consumer price level. The efficiency or otherwise of this policy is demonstrated by its effectiveness in forcing the consumer price and the price paid by the NHS rapidly down to the marginal cost, on which the results of this article cast more than reasonable doubt. The ability to show reductions in the consumer price in relation to the situation in which the entry of generic competitors was not allowed does not constitute a sufficient condition.

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