

Delivering generics without regulatory incentives? Empirical evidence from French general practitioners about willingness to prescribe International Non-proprietary Names

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Abstract

France presents a unique situation in which the take-off of a generic drug market depends, out of regulatory incentives, on whether physicians choose a prescription method (International Non-proprietary Names, INN) that can lead to the delivery of these drugs and on whether patients accept them. This paper is aimed at pointing out factors explaining general practitioners' (GPs') willingness to prescribe in INN through data collected from a Southeastern France representative sample of 600 GPs in March 2002. The main results shed light on the key-role played by GPs' information about drugs and the source which they take it from, by GPs' volume of services and caseloads, and slightly by socioeconomic characteristics of patients.

Key-Words

International Nonproprietary Names, Generic Drugs, General Practitioners' Prescribings, General Practitioners' Knowledge, Incentive Rules

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1. Introduction

Although drugs do not account for the highest share of health care expenditures in developed countries, public policies to control escalation of health care costs have focused considerable attention on pharmaceutical costs that have often been perceived as more amenable to reduction than other cost components such as hospital expenditures [1]. In many countries, policies to reduce pharmaceutical costs have included incentives and regulations to encourage the substitution of cheaper generic drugs to the prescription of their usually more expensive brand-name counterparts. Results of policies to encourage prescription of generic drugs however widely differ from one country to another [1-3]. In developed countries, diffusion of generic prescriptions seem to depend on the existence and types of financial and regulatory incentives that have been offered to physicians [4-6] and pharmacists [7]. It also depends on pressure exerted by patients in their role as consumers, which in turn varies with the amount of the co-payments required when their health insurance schemes do not offer total coverage of their drug costs [8-10].

In France in 2001, generic drugs represented only 6.7% of the volume and 3.5% of the value of prescribed drugs, a market totaling 14.760 thousand million euros [11]. Although the French drug market is highly regulated [12], unlike other European countries (for example, the United Kingdom, the Netherlands, and Germany), it does not include explicit incentives for encouraging French ambulatory practitioners to prescribe generic drugs [13]. French practitioners remain free to either prescribe a branded or a generic drug. However, if any practitioner delivers his/her prescription using the drug most general denomination, i.e. its international non-proprietary name (INN), the pharmacist is then authorized to deliver the prescription using a generic version of the drug (rather the brand-name product) if such version exists.

According to the literature, various factors may directly or indirectly influence physicians' willingness (or reluctance) to prescribe generic drugs [14, 15]. In order to avoid potential bias coming from impossibility for practitioners to prescribe INN due to the unavailability of generic drugs [15-17], we preferred to question physicians about their willingness to prescribe INN rather than about their actual prescriptions in INN. As long as the French legal framework gives free rein to physicians for prescribing INN, it seems crucial to acknowledge whether the weakness of the French generics market

relies on practitioners' lack of motivation and, as a result, to identify physicians' key-characteristics explaining it. In that case, the French strategy to promote generics through INN prescribing should have to be reconsidered.

A survey carried out in 2002 in a representative sample of general practitioners (GPs) of South Eastern France gave us the opportunity to test if these features play a similar (or different) role when it comes to prescribing by INN. GPs' socio-demographic and training characteristics, as well as their major sources of information and level of knowledge about drugs and their beliefs about the comparative merits of brand-named drugs and their generic versions may determine their prescribing behaviors. In addition, in a health care system such as the French one where ambulatory physicians are paid on a fee for service basis, prescribing by INN may require more time for each consultation and consequently negatively affect practitioners' revenue (or may create fear that this will happen if they change their prescribing habits from brand-named drugs to INN). Finally, patients' demand may influence physicians' patterns of prescription. On the one hand, patients who have limited out of pocket co-payments for drugs may exert pressure to obtain the brand-name drug. On the other hand, patients with low income and less insurance coverage for drugs may have an incentive to ask for prescriptions based on the least expensive drugs.

2. Material and methods

2.1. Data

2.1.1. Socioeconomic and health characteristics of the survey region

This article uses data collected from a representative regional panel of 600 ambulatory general practitioners in Provence (southeastern France), initiated in March 2002. In this region, the number of private practitioners in ambulatory medicine is respectively 140 for GPs and 131 for medical specialists per 100000 inhabitants (which corresponds to a higher density of medical practitioners compared to the national average- 114.6 and 85.2, respectively). Reimbursed healthcare expenditures averaged 1777 euros per year per inhabitant (national mean: 1439 euros) in 2002. Total non-hospital healthcare costs account for 669 euros per year per inhabitant (national mean: 534 euros), and drugs prescribed by general practitioners 337 euros (national mean: 258 euros) [18].

2.1.2. The physician sample

The sample was drawn from a population encompassing all 5450 private GPs practising in South-Eastern France (district of Provence, Alpes and Côte d'Azur, or PACA). The sample was obtained as a single-stage, random sample, stratified by GP's gender, age and size of the urban area containing the commune where GP practises (table 1). In each sampling strata a random draw of about a ninth of the whole population was performed. Among the approximately 1200 physicians asked for to participate, 1076 were eligible. 600 respondents were successfully enrolled (overall response rate was 55.76 %). Response rates slightly differ from a strata to another, but differences are statistically different neither for gender, age nor size of practice area (table 2).

Physicians who reported offering exclusively specific medical services (such as acupuncture, homeopathy, osteopathy) were excluded, as well as GPs intending to move outside the region or retire within the next 6 months. The 600 participants agreed to complete surveys twice a year for three consecutive years about their prescribing and care practices. This article is based upon results from the first survey, conducted from February to March 2002. Analysis of basic demographic characteristics suggested no significant difference between the 600 respondents and the whole population of 5450 GPs.

2.1.3. Data collected

GPs were asked to complete a 53-item questionnaire (mean completion time: 35 minutes) about GPs' professional and social characteristics, opinions and representations of public health problems and the specific nature of their work activities. One question specifically concerned their willingness to prescribe drugs by their INN ("Are you willing to prescribe INN?").

Since underlying socioeconomic and demographic characteristics of populations are often assumed to give rise to health care needs [19], and thus to demand for physician services, information extracted from municipal statistic databases concerning the physicians' practice settings, socioeconomic (population characteristics) and competitive (physician prevalence and density) was also used. These aggregate characteristics at the level of the commune population were obtained from the 1999 national

census [20]. The crude mortality rate in each physician's area of practice was recorded and used as a proxy of morbidity.

A binary variable of physicians' availability for more work was constructed from the hours of weekly work they reported and their expressed desire to reduce or increase their work time. This variable was coded as 0 if the working time weekly was less than desired, 1 if it was equal to or more.

Overall, we considered six groups of variables that could potentially affect GPs willingness to prescribe INN (appendix 1). These were basic fundamental demographic characteristics (age, gender, time in practice, size of town), determinants of their professional practice (billing sector, that is, if their fees are controlled or not, organization of work, relation with other healthcare professionals), their continuing education activities (additional degrees, participation in CME courses, reading of medical journals, meetings with pharmaceutical sales representatives), their reported activity, the competitiveness of their environment (prevalence of specialists, prevalence and density of general practitioners), and the socioeconomic environment of their practice (social and economic characteristics of the patient population).

2.2. Method

We carried out a logistic regression with willingness to prescribe INN as the dependent variable. Univariate regressions of the willingness to prescribe INN on each of the above mentioned regressors have been first computed. Explanatory variables which were related to the willingness to prescribe INN with a p value of 0.20 or less were then introduced into a multiple logistic model which considers the reduced form equation:

$$y_i = \zeta_0 + \zeta_1 X_{i1} + \zeta_2 X_{i2} + \zeta_3 X_{i3} + \zeta_4 X_{i4} + \zeta_5 X_{i5} + \zeta_6 X_{i6} + \kappa_i$$

with: $y_i = \begin{cases} 1 & \text{if GP declares to be willing to prescribe INN} \\ 0 & \text{if not} \end{cases}$

where X_{i1} , X_{i2} , X_{i3} , X_{i4} , X_{i5} and X_{i6} represent set of regressors related respectively to GPs' individual characteristics, GPs' medical practice, GPs' training effort and information sources, activity declared by GPs, competition with other physicians in the same area and aggregate measures of socioeconomic features of population in the practice area.

The model in turn was estimated by the maximum likelihood method, in a backward procedure. The threshold for excluding variables from the model was set at 0.10. Sex and age were forced in the final model as control variables.

A principal component analysis was undertaken on socioeconomic and demographic indicators about GPs' practice environment available (variables included in X_{i6} for GP i) in order to avoid multicollinearity problems, using a Varimax rotation and Kaiser normalisation [21] to determine the principal directions. For each of the principal factors we retained the variable having the most salient contribution. These variables were unemployment rate, crude mortality rate (the number of deaths per 1000 inhabitants), percentage of temporary jobs in total jobs, percentage of families with 4 or more children, and three variables covering home circumstances: percentage of public housing in the municipality, mean area per person in housing (square meters), and percentage of residences without washroom nor individual toilet.

3. Results

A total of 458 out of the 600 respondents (76.2%, 95% weighted confidence interval: [72.1%; 79.4%]) declared that they were willing to write their prescriptions using INN.

The null hypothesis of simultaneous nullity of all parameters in the equation is rejected, since the p-value of the likelihood ratio test associated to the final version of the estimated model equals .001. The fit of the model is equal to 81.3% which means that variables in the model help to explain GPs' willingness to prescribe INN, compared to the naive model which considers that every GP is willing to prescribe INN and performs 76.2% of good fit.

GP's gender, age, billing sector, length of practice, and additional degrees are not associated with this willingness. Nor were any of the following factors: competitiveness of the practice environment (private general practitioners per 100000 inhabitants and per immediate square kilometer), socioeconomic composition of the local population, unemployment rate or crude mortality rate table 3).

On the reverse, several factors are associated with a greater reluctance to prescribe INN. GPs who declare to work less than desired and not to consult guidelines made by the French Agency of Health Security and Products (AFSSAPS) have a probability to be anxious to prescribe INN reduced by about

30%. The first result is, however, near the limit of statistical significance. In the same time, GPs who did not pay subscription to at least two medical journals, nor have a computer in their office, are less likely to prescribe INN (probability of willingness to prescribe INN is reduced by about two third and 44% respectively). Having a practice which is not exclusively private is associated with a smaller reluctance to prescribe INN (probability of willingness to prescribe is increased by 84%). Meeting with not many pharmaceutical sales representatives (less than 10 per week) is also associated with smaller reluctance to prescribe by INN (probability to be likely to prescribe INN is increased by 56%). In GPs' socioeconomic environment, the smaller the percentage of public housing in the practice area is (less than 15%, which is the first quartile), the bigger the probability to be reluctant to prescribe INN is (probability is increased by 28%).

4. Discussion

4.1. Relation between willingness and actual prescription in INN

This paper examines physicians' reports about their propensity to prescribe by INN. Some studies reported figures very close to ours [16, 22]. Nevertheless, willingness to prescribe by INN is different from actual prescribing behavior. The substantial differences between self-reported intent and real behavior by physicians give some support to the necessity to distinguish GPs' motivation to prescribe INN through willingness to prescribe from actual declared prescriptions [16, 23]. In this study, three physicians in four state that they were willing to prescribe INN, but physicians' prescriptions lead to the sale of generics in this region in only 30.6% of the cases where a generic version exists [24]. Obviously, GPs are to cope with difficulties to prescribe INN which are not exclusively due to a lack of interest and which further studies will have to explore.

4.2. The role of information

By requiring the use of the name of the active ingredient rather than the brand name of the drug, prescription by INN requires doctors to change their prescribing habits substantially. It places the ultimate use of generic drugs at the end of a chain of decisions (physician's prescription by INN, pharmacist's suggestion of generic drugs, patient's consent).

It has been shown that the series of decisions by physicians and pharmacists that lead to the delivery of generic drugs depends on the physicians' knowledge of drugs that can be substituted for a brand-name

drug [25, 26]. In this survey, several informational variables were found to affect the physicians' intention to prescribe by INN: consultation of the leading prescription practice guidelines (AFSSAPS guidelines), regular reading of several medical journals, availability of a computer, which promotes access to critical information through the consultation of distant electronic resources. Other processes involved in the acquisition of professional knowledge may also promote a more favorable attitude towards INN prescriptions: participation in collaborative professional practices within health networks, a not exclusively private practice (that is, working some shifts in hospital departments). GPs seem to take informations about drugs from two quite different channels depending on drugs' age. GPs essentially use guidelines and hospitals recommendations when drugs are old, and more especially informations from pharmaceutical representatives when drugs are new [27, 28]. And yet, firms producing generics, which most often are newer than equivalent brand name drugs, devote much less money to inform GPs than firms producing brand name drugs [29]. On the reverse, the information physicians obtain from visits from drug company sales representatives seems to contribute to a greater reluctance by physicians to prescribe by INN. Specifically, physicians are much more sensitive to arguments about a drug's efficacy than about its price [30, 31]. Their representations of the efficacy of the brand-name drug and the generic drug often remain different. The information strategies, or marketing, directed at physicians by pharmaceutical companies, lead doctors to differentiate between these products, whether on an objective basis or not, and probably contributes to the belief that the brand-name is associated with better efficacy [32-37].

4.3. Patient influence in the drug decision

This article sought, for the most part unsuccessfully, to uncover a direct relation between the occupational and economic structure of the population in the neighborhood of the physician's practice and his or her willingness to use INN in prescribing. Only a few studies had clearly demonstrated the importance of the patient in the choice of drug [30, 38]. Despite the widespread belief that medical decisions are sensitive to patients' expectations [39], the choice of prescribed drugs appears to result essentially from the physician's own decision-making process [32].

Only the prevalence of (multiple-dwelling unit) public housing in the GP's neighborhood was found to be related with a practitioner's greater willingness to prescribe by INN. Of course we cannot exclude

that the other variables we have used as proxies to describe characteristics of GPs' clientele were too crude to capture effective factors related to demand for drugs. However, the relationship between a type of housing in GP's neighborhood and willingness to prescribe INN may be interpreted as an indirect manifestation of some social pressure exerted on the physician, promoting INN prescription, so that the prescription can be filled with generic drugs. The concentration of this type of housing is statistically associated with a lower per capita disposable income and is often an expression of local poverty [20]. The entire French population is supposed to be covered by mandatory health insurance financed on a national basis by payroll and self-employment taxes. The mean reimbursement rate for healthcare expenditures is approximately 75%. The reimbursement for drugs ranges, according to the type of drug and disease, from 35% to 65% to 100%. This insured population can also obtain supplementary voluntary insurance coverage that minimises the amount of the copayment for incomplete reimbursement by the mandatory public insurance. In situations where the individuals do not have any supplementary insurance, the physician may choose to prescribe the INN so that the patient receives a generic, less expensive, drug.

As for the patients' preference about the type of drug prescribed (brand-name versus generic), no real empirical evidence supports the common belief that patients could refuse generic drugs after receiving an INN prescription [30, 40-43]. In addition, the principal obstacle to prescriptions being filled by a generic rather than brand-name drug is the physicians' failure to provide information or explanation to the patient about this choice [44-46]. In a recent survey in France, 40% of those questioned said they were inadequately informed and 60% that they would like more information about the prescription and provision of generics. 83% said they would agree to have their prescription filled by a generic product after a prescription by INN [47].

4.4. Caseloads, volume of services, and variety of clinical situations

INN prescribing has been presented as requiring additional time for French general practitioners by its profound modification of their deeply ingrained prescribing habits. Logically then, physicians who declare having reached an appropriate working time should be more reluctant to prescribe INN, to the extent that they would either have a lower number of consultations and consequently a lower income or would be obliged to work longer time to maintain their income. Quite interestingly, we observed a

reverse phenomenon: physicians who declared to work more time than they would want turned out to be more disposed to prescribe by INN. These physicians were the ones with the greatest volume of consultations. Two potential explanations, which however data considered in this paper do not allow to test formally, could be stated.

First, GPs who declared higher weekly working time are likely to use drug prescriptions as a major form of patient management, and make a time trade off between examination and discussion on the one hand and prescription on the other [48]. Then, GPs who prescribe the most are more willing to prescribe INN than GPs who promote more non-drug treatment because they are more used to prescribe. A corollary point is that delivering generics is only possible when such a drug exists. If the opportunity for GPs to prescribe INN depends from the existence of generics (GPs will most often prescribe brand names otherwise), willingness to prescribe INN will rely on the variety of clinical situations encountered by GPs, which, as a matter of fact, can be assumed to increase with their caseloads. In this framework, the large volume of activity may increase learning effects, also making willingness to prescribe INN more likely, or at least more efficient [49].

Second, drugs prescribing may be viewed by GPs as one of the ways to compete. Considering the above arguments of GPs' beliefs about patients' preferences, GPs in the beginning of their career and/or GPs having smaller clientele (and smaller weekly working time), may think that prescribing INN, linked to delivery of generics, is detrimental to the preservation or the broadening of the clientele [38, 41]. Then, GPs with the smaller volume of services, albeit they are supposed to have more time to invest in the intellectual act of prescribing INN, may first consider their own economic interest through patients binding (maintaining or increasing activity to reach or exceed a previously set level of target income).

5. Conclusion

France presents a unique situation in which the take-off of a generic drug market depends basically on whether physicians choose a prescription method (INN) that can lead to the delivery of these drugs and on patients' willingness to accept them. The French experiment has been one of the rare attempts to develop the generics market without initiating various regulatory incentive plans. Retrospectively

and in comparison with other countries, this method may have slowed the development of generic drugs in France.

The French situation seems to make the sharing of information by physicians and patients the principal vector for the spread of generics. Other studies in other types of regulatory contexts have pointed out the need to reduce the suspicion that physicians and patients have towards these drugs. This survey reveals that in France the physicians' sources of information have a crucial importance in the decision to prescribe INN and that different forms of access to information can generate either willingness or reluctance to do so.

Since the end of the survey (March 2002), the private general practitioners in France have been required, as part of their contract with the national health insurance system, to prescribe more often INN in exchange for the fee increases granted to them (agreement of 5 June 2002). Moreover, France is experiencing since October 2003 reference pricing for a list of drugs which is to be enlarged soon. Accordingly we are now examining the extent to which physicians' beliefs and practices may change in this new context and have to be disentangled from consumers' preferences.

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Table 1: Sample structure

Age	Size of urban unit	Gender			
		<i>Men</i>	<i>% total</i>	<i>Women</i>	<i>% total</i>
<i>Younger than 42 years</i>	<i>Fewer than 20000 inhab.</i>	11	1.83%	3	0.50%
	<i>20000-200000 inhab</i>	39	6.50%	11	1.83%
	<i>More than 200000 inhab</i>	66	11.00%	20	3.33%
Total		116	19.33%	34	5.67%
<i>42-52 years</i>	<i>Fewer than 20000 inhab.</i>	23	3.83%	7	1.17%
	<i>20000-200000 inhab</i>	75	12.50%	21	3.50%
	<i>More than 200000 inhab</i>	142	23.67%	39	6.50%
Total		240	40.00%	67	11.17%
<i>Older than 52 years</i>	<i>Fewer than 20000 inhab.</i>	10	1.67%	3	0.50%
	<i>20000-200000 inhab</i>	34	5.67%	9	1.50%
	<i>More than 200000 inhab</i>	69	11.50%	18	3.00%
Total		113	18.83%	30	5.00%
OVERALL		469	78.17%	131	21.83%

Table 2: Response rates

		Gender	
Age	Size of practice area	Men	Women
Less than 42 years	Rural	66.67%	33.33%
	Less than 200,000 inhabitants	58.18%	52.94%
	200,000 inhabitants and more	48.94%	72.22%
Total		52.20%	64.29%
42 to 52 years	Rural	71.43%	63.64%
	Less than 200,000 inhabitants	60.58%	60.71%
	200,000 inhabitants and more	53.18%	65.22%
Total		56.05%	63.89%
More than 52 years	Rural	50.00%	66.67%
	Less than 200,000 inhabitants	51.06%	58.33%
	200,000 inhabitants and more	55.17%	44.74%
Total		53.85%	49.06%
Total		54.60%	60.37%

Table 3: Factors associated with GPs' willingness to prescribe INN (n=600)

				Simple logistic regression		Multiple logistic regression	
Characteristic	Categories	N	% INN	OR [95% IC]	p	OR [95% IC]	p
Sex	<i>Men</i>	470	77.40	1.34 [0.86-2.08]	0.20	1.24 [0.76-2.02]	0.39
	<i>Women</i>	130	71.50	1.00		1.00	
Age (years)	<i><44</i>	168	74.40	0.74 [0.43-1.27]	0.27	0.62 [0.35-1.11]	0.10
	<i>44-48</i>	152	76.30	0.82 [0.47-1.43]	0.49	0.72 [0.40-1.29]	0.27
	<i>49-52</i>	142	74.60	0.75 [0.43-1.31]	0.31	0.65 [0.36-1.18]	0.65
	<i>>=53</i>	138	79.70	1.00		1.00	
Working as much as desired	<i>No</i>	160	69.90	0.67 [0.44-1.01]	0.05	0.71 [0.45-1.10]	0.12
	<i>Yes</i>	440	77.80	1.00		1.00	
Private practice exclusively	<i>No</i>	111	84.70	1.92 [1.10-3.34]	0.02	1.84 [1.03-3.29]	0.04
	<i>Yes</i>	489	74.20	1.00		1.00	
Uses AFSSAPS guidelines	<i>No</i>	183	71.00	0.68 [0.46-1.00]	0.46	0.70 [0.46-1.08]	0.10
	<i>Yes</i>	417	78.40	1.00		1.00	
Number of journal subscriptions	<i>None</i>	352	73.00	0.33 [0.16-0.68]	0.00	0.34 [0.16-0.73]	0.00
	<i>1</i>	165	76.40	0.39 [0.18-0.86]	0.02	0.36 [0.16-0.81]	0.01
	<i>2 or more</i>	83	89.20	1.00		1.00	
Has a computer	<i>No</i>	81	65.40	0.54 [0.33-0.89]	0.02	0.56 [0.33-0.96]	0.04
	<i>Yes</i>	519	77.80	1.00		1.00	
Drug reps/week	<i>< 10</i>	462	78.60	1.72 [1.13-2.62]	0.01	1.56 [0.99-2.43]	0.05
	<i>>= 10</i>	138	68.10	1.00		1.00	
% public housing (multiple dwellings) in municipality	<i><15.05</i>	450	75.08	0.79 [0.50-1.01]	0.05	0.72 [0.45-1.00]	0.05
	<i>>=15.05</i>	150	79.30	1.00		1.00	

Appendix 1: List of explanatory variables

Physicians' demographic characteristics (X₁)

Sex
Age
Time in practice
Number of offices
Size of municipality where office is located

Medical practice (X₂)

Billing sector
Solo practice/ group practice
Member of a network
Relations with other health professionals
Particular type of practice
Has a computer
Has an internet connection
Has a secretary or answering service
Satisfaction with practice

Training and information sources (X₃)

Other degrees
Consults AFSSAPS (French Health Products Safety Agency) guidelines
Paid subscription to medical journals
Number of drug reps seen weekly
Number of CME sessions

Reported activity (X₄)

Weekly work hours
Exclusively private practice
Works as much as desired

Competitive situation in municipality (X₅)

Prevalence of general practitioners (/100000 inhabitants)
Prevalence of specialists (/100000 inhabitants)
Geographic density (general practitioner/km²)
Proportion of market (active caseload/potential caseload)

Socioeconomic environment of practice municipality (X₆)

Percentage of temporary jobs in total jobs
Unemployment rate
Percentage of public housing in the municipality
Mean area per person in housing
Percentage of residences without washroom nor individual toilet
Percentage of families with 4 or more children
Mortality rate (deaths/municipal population) per 1000 inhabitants