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Quality Safeguards and Regulation of Online Pharmacies

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Quality Safeguards and Regulation of Online Pharmacies

Abstract

Using econometric evidence, this article confirms that distribution of medicines online is split into two market segments of very diverse quality, and identifies the factors that drive quality and quality assurance in this activity. Unlike fraudulent, 'rogue,' websites, which offer scant guarantees and usually sell just a few medicines without prescription, online pharmacies offering insurance coverage and linked to conventional pharmacies typically sell a whole range of drugs, require third-party medical prescriptions and provide abundant information to patients. It is shown that, where online pharmacies are allowed to act legally, market forces enhance quality, as private insurers require professional standards, and specialized third parties make a business of certifying them. Furthermore, older online pharmacies and those running conventional operations offer higher quality, probably because of reputational investments. Overall, this evidence supports licensing online pharmacies, especially considering that prohibiting them is ineffective against fraudulent sites.

Keywords: E-Commerce, Pharmacies, Quality Assurance, Regulation, Transaction Costs.

JEL: I11, I18, K23, L15, L84.

1. Distribution of medicines via the Internet

Online pharmacies challenge existing market structure for the retail sale of medicines. Policy-makers find it difficult to deal with such a new form of distribution, because, despite its benefits, its functioning is poorly understood, it poses new risks and it may conflict with vested interests. This article clarifies some of these issues by showing how and why existing online pharmacies offer different levels of quality and suggesting how the regulation could be adapted to deal with them more effectively.

The rest of the article proceeds as follows. The remainder of this section describes how online pharmacies work, paying particular attention to their regulation, the diverse quality of their services and the risks they involve. Section 2 devises an analytical framework to explain which factors determine the level of quality and establishes several hypotheses. According to these, service quality and information provision are positively related to licensing and insurance coverage and to the reputation of the website operator. These hypotheses are confirmed by a series of empirical tests in section 3, run on a purposely-built sample of online pharmacies. Section 4 concludes with some policy recommendations and suggestions for further research. In particular, results support lifting the prohibitions on online pharmacies and using public regulators, health insurers and third-party certifiers to drive this activity to the desired level of quality. This might even, indirectly, curb the current underground trade by fraudulent online operators, known as 'rogue sites.'

1.1. Different regulations and weak enforcement

In the USA, online pharmacies have been allowed to operate on essentially the same basis as ordinary 'brick and mortar' pharmacies (Goetz and Lund, 2000). This freedom, together with greater development of the Internet and more fragmented and market-driven health care and insurance, has allowed online distribution of medicines to become relatively more developed there.

In contrast, only three European countries (Denmark, Netherlands and the UK) allow distance selling of medicines. According to the e-commerce directive,[2] the pioneer online pharmacies established in these countries are supposedly allowed to sell to buyers from other countries of the EU. However, national authorities are increasingly constraining such practice. A prominent example can be seen in the Doc.Morris case in Germany, still under litigation.[3] Paradoxically, the European Union strives to facilitate e-commerce by all means (European Commission, 1999, 2001) except, in the case of e-pharmacy, for lifting the regulatory constraints that make it impossible in most of its member countries.

Given the difficulties for effective enforcement, prohibition of online pharmacies has not stopped illegal trading, however. Enforcement is seriously hindered in e-commerce because it breaks the territorial correspondence between enforcers and the regulated. Providers are difficult to control when their presence in the territory is confined to the computer screen of users. The end result is that prohibition hinders the existence of reliable online operations and not only protects conventional pharmacies but may also indirectly benefit rogue sites, as an increasing number of customers use them to buy legal medicines that could be provided by reliable online sellers, if only they were allowed to operate.

1.2. Different standards of practice

Two factors, therefore, determine the odd structure of this market with respect to quality of service. Firstly, some countries have allowed licensed online pharmacies to be created.

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[2] See Bordoni (2001, 2). Three EU directives are involved in defining the regulatory environment of European online pharmacies. In principle, Directive 2000/31/EC on electronic commerce enables providers to serve consumers in all EU member States, and Directive 97/7/EC on distance selling makes it possible to deliver prescription medicines by mail. However, they may be superseded by national laws which, with the excuse of protecting public health and consumers, may in fact be protecting local and conventional providers. The stringent regime set by Directive 95/46/EC on data protection might also unnecessarily constrain the efficient use of consumers' databases, an important comparative advantage of online pharmacies (Twibell, 2000a). A more general analysis of the comparative prospects faced by online pharmacies in the US and the EU is given in Twibell (2000b, 158-95).

[3] See Weber (2000) and Zwick (2001) on this case, and Twibell (2000a) for a description of the business strategies of three other pioneer European online pharmacies: the British Pharmacy2U, Allcures.com and the Swiss Pharmaworld.com.

Secondly, enforcement of prohibitions to sell medicines online from unlicensed sites is weak in all countries, due to the novelty and difficulties of controlling e-commerce.

The simultaneous presence of licensing and ineffective enforcement leads online distribution of medicines to split into two market segments, with very diverse levels of quality: one segment of high-quality online pharmacies and another of rogue sites. Their standard processes can be described by reference to their extreme types.

High-quality online pharmacies are licensed and comply with regulations like any other pharmacy, from which they differ only because they serve their customers online. Typically, each user first opens an account, so must send in the details of his credit card and medical insurance. After registration, each patient is assigned to a specific team of pharmacists; then, either the patient or his doctor sends in a valid prescription by conventional mail, fax or, increasingly, by certified e-mail. The pharmacy then sends the medicines by mail from a central warehouse or from a conventional pharmacy close to the patient's home from which the patient may also collect them personally. Medicines usually take two or three days to arrive for which the patient does not incur additional mail costs, or can be delivered in 24 hours at a special cost for urgent delivery. Most of these pharmacies also have permanent channels of communication so that customers can consult their pharmacists either by a free phone service or by e-mail (Henkel, 2000; Heinrich, 2000).

Low-quality sites, on the contrary, substitute independent medical prescriptions by online questionnaires of doubtful effectiveness. Some operators even advertise the fact that no prescription is required. ("No prescription? No doctor? No problem"). Those that use questionnaires ask patients for basic personal details, such as their age and whether they are following any treatment or have any allergies, or whether they have a family or personal background of certain illnesses, such as heart disease and cancer. They then provide a text in which they explain that, in order to make the purchase, the customer must be over 18, they recommend patients to consult their doctors about the use of the drugs and, finally, they ask the patients to accept liability for the consequences of the purchase and use of the medicines. Most of these sites state that the questionnaires are checked by a doctor who decides on whether or not the medicine is appropriate and whether the order should go through or not.

1.3. Advantages

The purchase of medicines via the Internet, as with other types of electronic commerce, can be very beneficial for consumers in terms of service and, less clearly, prices.

Online pharmacies provide added convenience and new services. Users enjoy greater availability in terms of opening hours, are able to substitute user travel by mail and can carry out comparative shopping, with a wider variety of products and enhanced access to product information and privacy (Henkel, 2000; Zbar, 2000). Online pharmacies offer completely new services such as sending electronic messages to remind patients to take their medicines at the right times or in the correct dose.[4] They also maintain exhaustive records on their patients, with details of the medicines they consume, their complaints and any contraindications, and this allows them to provide a better-quality service and to collaborate efficiently in tests on new drugs and in clinical trials. Benefits also extend to other parties, who may attain substantial savings in administrative costs (Scanlon, 2001). A report to the European Commission thus considered them cost-effective (Gambardella, Orsenigo and Pammolli, 2000, 61). Certainly, the advantages of Internet distribution vary according to the type of product on offer. Being small, lightweight and valuable, most drugs are ideal for all types of distance selling, especially electronic commerce. But e-commerce is most useful for users when their complaints are easy to identify and when talking about them to the doctor or requesting them personally in the pharmacy may be a source of embarrassment. On the other hand, drugs which are well-known by patients and which are not covered by health insurance are easy to buy on-line. Obviously, sales in online pharmacies are mostly for non-urgent drugs,[5] especially when patients can estimate demand in advance as with chronic illnesses.

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[4] For example, the services offered by the CVS-Merck-Medco on-line pharmacy included the following in September 2000: "Coverage and pricing comparisons for brand-name and generic medications for both mail service and retail; point-and-click refills and renewals; 12 months of mail service and retail prescription history with or without drug name display—you choose!; manage your household's account; personalized health topics and tools—based on your expressed interests; time-saving nonprescription shopping lists" (http://www.merck-medco.com/medco/index.jsp).

[5] CVS, an US leader in both conventional and online pharmaceutical retailing, estimates that half its prescription sales contain some element of urgency and will never be sold online ("Batalla de precios en Internet," *Diario Médico*, January 13, 2000).

Such factors explain the success of on-line sales of Viagra and 'lifestyle drugs' which assist in problems of obesity, balding and the like.

A recent survey of scientific studies concludes that online markets are more efficient with respect to price levels, price updating and price elasticity. They suffer greater price dispersion, however, possibly explained by heterogeneity in levels of trust and buyers' knowledge, and are still in a developing stage (Smith, Bailey and Brynjolfsson, 2000). Similar results have been observed for online pharmacies, which seem to offer lower prices than their conventional counterparts. Trade journals report discounts of between 10 to 30 per cent over prices in the real pharmacies belonging to the same companies. Moreover, many pharmacies provide additional means of comparing prices, offering very substantial savings for consumers.[6] Such figures refer to direct discounts for users. In the case of customers covered by health insurance schemes, the discount takes the form of a lower co-payment. In addition, the insurer usually receives an additional, larger discount. Although, in principle, the user does not benefit from such discounts to insurers, in the long term the latter take them into account when setting the premiums of their policies so that users purchasing their medicines on-line should end up paying less for their policies.

1.4. The presence and extent of risk

From a public interest viewpoint, the sale of medicines via the Internet represents a threat in that it easily escapes the conventional system of regulation, with dual control by both doctor and pharmacist, whatever its real merits. In fact, in many online sales, either the doctor's prescription or the involvement of a pharmacist, or both, are eliminated. This happens when the patient purchases the medicines directly, without a prior consultation, with no clinical action by the online seller or with any action being based on personal questionnaires that are difficult to verify and are of limited efficacy. Thus the doctor cannot identify contraindications, the patient receives no information and the pharmacist cannot detect harmful interactions or educate patients (Armstrong, Schwartz and Asch, 1999).

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[6] Of up to 799 per cent as with ranitidin: 60 tablets of Zantac cost 98.70 dollars in October 2000 in Drugstore.com, a certified pharmacy, whereas it sold the same amount of generic ranitidin for 10.98 dollars (accessed October 15, 2000).

The existence of doubtful suppliers has been pointed out in many empirical studies. In one carried out in 1999 on 77 online suppliers of unprescribed Viagra, the price was seen to vary between 5 and 50 dollars, the average price being 12.60 dollars. Some suppliers charged an average of 64 dollars for carrying out a health questionnaire. 40 per cent, most of them outside the United States, did not request any medical information from the purchaser and those that did requested it in a way that was difficult to understand (Armstrong, Schwartz and Asch, 1999). Of the 22 pharmacies identified in a more specific study that aimed to estimate to what extent Viagra was being sold via the Internet for patients with contra-indications (Eysenbach, 1999), 2 required a written prescription from a doctor, 9 dispensed Viagra without a prescription at all and 11 issued an 'online prescription' after a so-called 'doctor' had examined a clinical questionnaire. The simulated purchaser was a woman aged 69, with difficulty in experiencing orgasm, obesity, coronary insufficiency and high blood pressure and who was taking captopril, pravachol, athenolol and erythromycin. She requested 66 pills from 10 of the 11 pharmacies requiring a questionnaire, 8 of which were based in the United States. Three of these companies sold the pills, in spite of the serious contraindications, and seven rejected the order.

The operation of these rogue sites, seemingly selling drugs of dubious quality without effective control, has subjected the sector to heavy criticism. Experienced regulators of online pharmacies have a more nuanced view, however. First, it is clear that the main problems of e-commerce medicine sales come from the poor-quality service provided by fraudulent online operators, who use the new sales channel to carry out illegal transactions, selling unapproved, contaminated, false or expired drugs (Henkel, 2000). Furthermore, not only are such practices far from being general, but their health effects are unclear. Even the FDA accepts that there are very few known cases of real damage being caused by the sale of medicines on line (Henkel, 2000). It seems that such rogue sites do not sell narcotics, stimulants, depressants and anabolic steroids that are controlled substances regulated in the US by the Drug Enforcement Administration.[7] To make things even more ambiguous, allowing users to get round regulatory obstacles is not always inefficient. This may well be the case when regulators get into the habit of delaying authorization of new medicines as a silent way of saving pharmacy costs.

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[7] "Prescription for Trouble" (*Consumer Reports*, February 2001, **66**[2], 19-22).

What seems clear, in any case, is that the risks associated with rogue sites are not present when dealing with high-quality online pharmacies. These may even provide better quality and control than conventional European pharmacies. First, because online pharmacies enjoy more powerful incentives to comply due to their larger scale, the role of reputation (when compared to the typical European pharmacy owned by an individual) may take on greater importance, and policing their behaviour is easier. Second, their technology also allows them to provide a service of high quality. The main alleged defect of online pharmacies in this respect is the lack of direct contact between patient and pharmacist. Personal contact certainly diminishes, but this does not necessarily imply a reduction in clinical activity. Personal consultation is always restricted for reasons of cost whereas the online pharmacy reduces the cost of communication and therefore increases its intensity. For example, it may be less costly for many patients to ask for advice by e-mail than in person and it may be more convenient for the pharmacist to use the same method because it enables him or her to schedule his time better. This, together with a wider use of computer databases, may increase the amount and quality of professional advice instead of reducing it.

2. Analytical framework

2.1. Quality assurance and testable hypotheses

The economics of quality assurance is based on distinguishing a set of specific problems and safeguards. Problems are defined in terms of the type of information asymmetry extant between the parties and their unique or repetitive interaction (Tirole, 1988, 106-26). Safeguards are mainly based on the threat of losing quasi-rents linked to previous investments in real or reputational assets (Klein and Leffler, 1981; Shapiro, 1983).

Most medicines present a mix of ‘experience’ attributes (Nelson, 1970), whose quality is only known after consumption (pain relief, delivery time), and ‘credence’ attributes (Darby and Karni, 1973), for which quality is never known (hidden effects). This, together with the need of expertise for the evaluation of attributes, generates substantial scope for information

asymmetry. This asymmetry is the main reason behind normative arguments for licensing and other conventional regulation. Licensing not only controls quality directly but it also defers compensation, by creating a stream of quasi-rents that helps prevent the provision of low-quality services to uninformed users.

In the case of online pharmacies, identical mechanisms are in place for pharmacies which are licensed by a public agency or whose sales are covered by insurers. Both of these decisions, licensing and providing insurance coverage, are made by third parties with an interest in avoiding low quality. Both also create quasi-rents to the extent that losing a license or the coverage of insurers would cause substantial losses.

In addition, two other drivers of quality may be present as a consequence of pure market forces. First, some online pharmacies put great amounts of reputational capital in play, the value of which would be destroyed if they were caught cheating. This is clearer for those which also run conventional operations and cover their online operations under the same reputational 'umbrella.' Second, older online pharmacies can be expected to provide greater quality because of reputational and learning effects. On the one hand, given the presence of experience attributes in the purchase of medicines, reputation will tend to accumulate with each instance that an online pharmacy delivers on its promises so, the longer a pharmacy is in business, the better known and more valuable its trade name will be.[8] On the other hand, substantial learning economies can be expected in a new activity like this, and these economies will also be greater in older operators.

In summary, the following four hypotheses will be tested in this article:

1. *Pharmacy type:*
   Two types of online pharmacies deliver widely different quality.
2. *Insurance coverage:*
   Quality is higher for pharmacies with insurance coverage.
3. *Reputation extension:*
   Online quality is positively related to reputational capital.
4. *Age effect:*
   Quality is positively related to the age of the pharmacy.

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[8] See Lafontaine (1992), Thompson (1994) and Arruñada, Garicano and Vázquez (2001) for a similar interpretation of age as a proxy of reputation in the service sector.

2.2. Data and methodology

A specific sample was built to test these hypotheses. It was drawn up by compiling the most outstanding characteristics of all online pharmacies listed by the Yahoo search engine.[9] The information was obtained by direct visits and examination of their web sites during the months of February and March 2001. Visits were repeated for consistency in June 2002 and changes observed were not statistically significant.

Business practices of online pharmacies were measured based on 17 attributes, each represented by a dependent variable, and three additional indices built from them. Table 1 defines the variables considered and summarizes the descriptive statistics. Attributes considered are of three kinds: service quality, information and third-party certification.

First, the quality of services provided takes into account the following: if the pharmacy requires an independent prescription (*PrescRqd*), without relying fully on an internal questionnaire or not requiring any prescription at all;[10] if it is willing or not to sell in foreign markets products requiring a prescription (*FrgnSales*); if it sells or not other products in addition to medicines (*OtherPrd*); the number of different products it sells (*Products*); and if it sells or not generic drugs (*Generics*). In addition, the cost of express delivery service (*UrgntFee*) is also considered. All these variables (with the exception of the urgency fee, because of the lower number of observations available) were used to build a global index of service quality (*QualIndex*) using principal components analysis, as reported in Table 2.

Second, the information supplied to users is proxied through five dummy variables. Three of them represent the different kinds of information channels, consisting of a phone line or e-mail address to deal with problems related to purchases and deliveries (*PhoneLine* and *E-mail* variables respectively), or a service that allows buyers to consult about the use of medicines

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[9] In http://dir.yahoo.com/Business_and_Economy/Shopping_and_Services/Health/ Pharmacies/. Six further pharmacies found using Altavista were added. No others were found using other search engines. All the pharmacies that sold more than one product were taken into account. For those offering a single product, a sample of 39 observations was taken, giving a sample error of one per cent. Internet sites that only offered information or sold over-the-counter products were excluded.

[10] Giving three values to this variable for distinguishing these two possibilities did not make any significant difference.

(*AskPharm*), plus the total number of information channels available (*InfoIndex*). Two other dummies consider the provision of pricing information, either through lists of prices (*PriceLis*) and/or price comparisons with competitive pharmacies (*PriceCom*). An index of information quality (*InfoIndex*) has also been built using principal components analysis (weights are given in Table 3).

Third, external certification of quality is measured considering the availability of each different accreditation via specific dummies (*VIPPS*, *HON* and *VeriSign*) that take value one when the pharmacy holds the corresponding certification, zero otherwise. The total number of certifications held by each site (*Certifcs*) is also measured, adding five other certificates that are less common to these three.[11]

The first hypothesis—on pharmacy type—will be tested using the variables in the previous sets of attributes, while the three quality factors that define hypotheses two to four will be proxied as follows. In the second hypothesis, licensing and insurance will be measured by third-party insurance coverage, *InsurCov*, a dummy that takes the value of one if insurers cover purchases of medicines in this pharmacy, and zero otherwise. This assumes that third-party insurers would not be willing to pay for purchases in unlicensed pharmacies. This is somehow stricter than mere licensing, but gets rid of potential difficulties caused by the use of variable standards of rigor in licensing decisions, mainly where these decisions are made by regional or state authorities. The assumption is also supported by the evolution of online pharmacies in the US, in whose success insurers played an essential role (Woldt, 1999; Scanlon, 2001). In the third hypothesis, which tests whether service quality increases with reputation, reputation will be proxied by *RealAssets*, another binary variable that takes value one when the firm also runs a conventional pharmacy operation, and zero if it operates only through the Internet. This variable, therefore, captures reputational spillovers from or to 'brick and mortar' activities.[12] In addition, the existence of such spillovers will also be examined by

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[11] See the following sites for information: http://www.nabp.net/vipps/intro.asp, http://www.hon.ch/HONcode/Conduct.html and http://www.verisign.com (visited September 4, 2001). To obtain a VIPPS certification, which is the most important, an online pharmacy must meet 17 criteria about patient confidentiality, prescription security, quality assurance, and patient-pharmacist consultation (Fisher, 2000).

[12] Lack of data on alternative reputational investments, such as advertising in launching the online operation, is not likely to be a major problem in this case, given the relative values of the assets involved.

checking the prediction that pure online pharmacies rely more on third-party certification. Finally, the joint effect of accumulated reputational investments and learning economies, posited in the fourth hypothesis, will be measured by the time the seller has been operating online, measured in years (*PharmAge*).

The empirical analysis will be based on several methods. Firstly, a cluster analysis will be used to identify well-separated groups in the sample. These groups will then be tested by comparing their means in order to confirm the typological hypothesis. Secondly, quality attributes of online pharmacies will be regressed on three independent variables (*InsurCov*, *RealAssets* and *PharmAge*) which are provisionally considered as exogenous, paying special attention to the existence of one-way causations by dummy variables (structural zeroes). Thirdly, a system of structural equations will be estimated to check that the results are not substantially affected by potential endogeneity of any of the independent variables.

3. Results

3.1. The diversity of online pharmacies

The descriptive statistics presented in Table 1 already show the diversity of business practices followed in the sale of medicines through the Internet. Insurers cover purchases in 19.47% of all the online pharmacies in the sample. A minority (13.27%) also run conventional operations. On average, they had been open for slightly more than one year (13.7 months), with a maximum of seven years. A doctor's prescription is required by 30.09% of them. Only a few (14.16%) sell other products in addition to drugs but most of them (70.19%) are happy to sell in foreign markets. Around a third (31.86%) carry a full range of

drugs,[13] in contrast to another third (33,63%) who carry only one product, with the remaining sites carrying between 2 and 29 drugs with an average of 7.26. It is possible to buy generic drugs in 14.16%. The average fee for express delivery was $17.25, with a range between $7 and $26. More than half the online pharmacies in the sample (52.21%) maintain telephone assistance lines and 34.51% of them provide access to a pharmacist. Price lists were provided by almost all sites (95.58%), while only 6.19% offered price comparisons. VIPPS certification was held by 8.85%, with lower numbers for *HON* (5.31%) and *VeriSign* (7.83%).

To explore the data in a more systematic way, a cluster analysis was performed using hierarchical agglomerative average linkage clustering. The resulting dendrogram (Figure 1) shows that pharmacies in the sample gather neatly into two groups, which are well separated by a large dissimilarity gap. Table 4 shows the descriptive statistics of these two groups. The fact that the high-quality group presents significantly 'better' means in all relevant dimensions strongly supports the typology hypothesis.

3.2. Determinants of quality

The regression models also confirm the hypotheses about the impact of insurance coverage and reputation on quality. In particular, results presented in Tables 5 and 6 show that the three independent variables explain a substantial share of the variability observed in the quality of service, the availability of information channels and the supply of third-party quality certification. Most strongly, all three dependent variables are positively related to insurance coverage. Without inferring the direction of causality (more on this below), those pharmacies with insurance coverage are much more likely to require a prescription, not to sell in foreign markets, sell other products in addition to drugs, sell a wider variety of drugs and charge less for urgent delivery. They also tend to provide more information. In particular, they tend to offer information on the use of drugs ('Ask the pharmacist'). Moreover, they are more inclined to have their quality independently certified by a third party.

[13] For these, a value of 100 was taken. The signs and statistical significance of the parameters and the model did not change when other assumptions (35, 1,000 and 10,000) were introduced.

Insurance coverage shows such an unusually high explanatory power that, as detailed in Table 5, one of the values of some of the dependent variables (*PrescReq*, *PhoneLine*, *E-mail*, *AskPharm*, *VIPPS*, *HON*) is fully determined by the *InsurCov* variable. In particular, all online pharmacies in which purchases can be charged to insurers require an independent prescription, provide an 'Ask the Pharmacist' information service and receive queries via e-mail. Similarly, *VIPPS* and *HON* certificates are found only in pharmacies in which drugs can be charged to insurers.[14] As a consequence, logit models for variables with such one-way causation are estimated by dropping the variables with zeroes and excluding the observations fully determined by the dropped variables, in order to avoid biasing the remaining coefficients. This affects models (2), (9), (10), (14) and (15) in Table 6, in which the absence of a coefficient, instead of indicating a lack of statistical significance, means quite the opposite: a certain relation between the corresponding dependent and independent variables.

There is also a positive connection between most of these quality factors and the fact that firms also operate conventional pharmacies. What's more, all online pharmacies running conventional operations also require prescriptions, as described in Table 5, causing another case of structural zeroes. They are also less likely to sell prescription drugs in foreign markets, and they stock more products and generics, and provide better information to users. As predicted, they are, however, less likely to be certified, probably because they use the reputation of their conventional operations to distinguish them effectively from rogue sites. Internet certificates seem to act as a substitute for extending pharmacies' reputation from the conventional to the online segments of the market. (This effect on third-party certification, which is not statistically significant for the full sample, becomes significantly negative when considering the interactions with age, as shown in Table 7).

Thirdly, the age of the online operations is strongly related to most of the dependent variables. Older online pharmacies are more likely to require a prescription, sell products other than medicines, carry a full line of medicines, sell generics and be certified. Specific

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[14] In this sample, it seems sensible to interpret the lack of observations with certain characteristics (zeroes in Table 5) as being 'fixed zeroes' (i.e., 'structural'), which are impossible to observe, instead of as 'random' ('sampling') zeroes, which might have simply remained unobserved in the sample (Hosmer and Lemeshow, 2000, 135-140). The reason lies in the additional adverse selection and moral hazard that would arise when insuring medicine expenditures without requiring that prescriptions be provided by independent third parties.

analysis using interactive variables shows that the effect of age on quality of service is concentrated amongst pharmacies operating only online (Table 7). Similarly, third party certification is more likely for older sites without insurance coverage or conventional operations. This is consistent with the idea that pure online players increase their quality with time but conventional firms diversifying online or linked to insurers start their operations by providing a high-quality service.

Coefficients in all models are not only statistically significant but also economically significant. For instance, insurance coverage and running conventional operations increase the quality index level in half and one third, respectively, of this index's full range. The effect of pharmacies' age is also substantial, with only five and nine years being necessary for age to produce a similar impact to that of insurance and running conventional operations, respectively.

3.3. Endogeneity of quality determinants

The previous section assumed that all the independent variables were exogenous. This allowed us to analyse service quality, information and certification attributes at the level of specific variables. The analysis, however, could be affected by the endogenous nature of two of the independent variables—insurance coverage and certification. When pharmacies decide on their strategy and quality, they are likely to take into consideration both insurance coverage and insurers' and certifiers' requirements. However, insurers and certifiers also consider pharmacies' quality when deciding if they are going to cover purchases by their insured parties in a specific pharmacy or grant them a quality certificate.

To check for the possible effects of endogeneity, a system of structural equations was estimated using three-stage regression. The equations consider the three independent variables, the service quality index and the certification and information indices used in the previous econometric analysis. The equations are:

$$
\begin{aligned}
QualIndex &= \beta_1 + \beta_2\, InsurCov + \beta_3\, RealAssets + \beta_4\, PharmAge + \varepsilon_1 \\
Certifcs &= \beta 5 + \beta 6\, InsurCov + \beta 7\, RealAssets + \beta 8\, QualIndex + \varepsilon 2 \\
InsurCov &= \beta 9 + \beta 10\ \ QualIndex + \beta 11\, Certifcs + \beta 12\, InfoIndex) + \varepsilon 3
\end{aligned}
$$

The results, presented in Table 8, confirm the analysis in the previous section—in particular, the positive effect of insurance coverage, running conventional operations and pharmacies' age on service quality. Also, the propensity of pharmacies with insurance coverage and without conventional operations to submit themselves to third-party certification. Lastly, as expected from the endogeneity rationale, quality of service and information positively affect the likelihood of a pharmacy offering its customers reimbursement from its insurers.

4. Policy discussion

This article shows that the online pharmacy industry is split into two segments of poor and high quality, as a consequence of the simultaneous presence of rigorous licensing in some countries and ineffective enforcement everywhere. It also identifies the determinants of quality provision of services. In particular, it finds that quality is higher for pharmacies with insurance coverage, those which also operate conventional pharmacies and those which have been open for a longer time.

These results suggest that provision of high-quality service in this industry is possible, can be regulated by public intervention and can be powered by market forces. Possibility has been demonstrated by the functioning of licensed online pharmacies. The efficacy of regulation has been indirectly shown by the significant impact that insurance coverage, a close proxy of public licensing, has on all measures of quality. Finally, the importance and compatibility of market forces is also clear, as quality is also driven by reputational investments linked to reputational spillovers (proxied through the simultaneous running of conventional operations) or accumulated over time through compliance with the promised levels of quality (proxied by pharmacies' age).

This interpretation supports the lifting of the current prohibitions of this activity in most European countries. Such liberalization would facilitate the benefits of electronic commerce in this area without causing any drop in service quality. On the contrary, the current activity of fraudulent sites would probably be hindered by the functioning of licensed online pharmacies, as the later would take part of the current demand of fraudulent sites.

Liberalization and licensing of online pharmacies are also compatible with the current systems of protective regulation, whatever their real merits are. The regulatory framework for online pharmacies would therefore be stricter than that for other online operations which are regulated by rules applying the electronic commerce Directive (00/31/EC). It could be similar to that for conventional pharmacies, including equivalent quality assurance, insurance coverage and corrective policies consisting of entry barriers and minimum standards of quality and service. If deemed necessary, it is also possible to incorporate online pharmacies into cross-subsidy schemes, thus reducing the impact on existing pharmacies.

Finally, our empirical findings also suggest that normal market forces are working in this online market towards the development of conventional market-driven assurance mechanisms, based on the reputation of market participants and specialized third parties. It has been shown, first, that insurers demand quality of service. Secondly, firms diversifying into online operations start out by providing higher quality, probably to capitalize on their reputational assets. Thirdly, pure online operators and those without insurance coverage are more likely to use private third-party certification than those also running conventional pharmacies. Lastly, the quality of purely online operators tends to improve with age. These findings advise a prudently patient regulatory attitude, as markets need time to develop safeguarding institutions adapted to the possibilities of new technologies.[15] Overall, and given also the difficulties to enforce prohibitions effectively, regulators should probably focus their activity on the setting of standards and the education of consumers. To some extent, this is what the US Federal Drug Administration has been doing with respect to e-pharmacies—in addition to investigating and prosecuting criminal activity, it has been busy in requiring quality certifications, intimidating rogue sites with 'cyber' letters and educating users in sound Internet purchasing practices.[16]

Many issues remain open for further research, however. In particular, future studies would benefit from additional information on the strategies followed by new entrants and

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[15] Time is needed also for designing the services with the highest value, as shown by some surveys of online shoppers (Yang, Peterson and Huang, 2001), probably because of the substantial change implicit in e-commerce. It is hardly surprising, then, that developing effective safeguards also takes time.

[16] See details of these activities of the FDA in http://www.fda.gov/oc/buyonline/ (visited September 4, 2001).

pharmacies' actual performance. For instance, information on advertising expenditures—an alternative source of reputational capital—would make it possible to examine in greater depth the comparative advantage that firms also running conventional pharmacies seem to enjoy over those that only operate online. Secondly, on the issue of performance, the article has relied on evidence from the services offered by online pharmacies to estimate the effects of quality assurance mechanisms. This evidence nicely complements studies that examine the quality of online pharmacies via a sample of real purchases, gathering data on the actual prices and quality provided. The integration of both approaches, however, would be a promising avenue for future research. By combining information on quality assurance and performance, such integration would make it possible to test whether quality assurance explains not only the quality offered but also actual quality. It would also allow the net benefits for consumers to be gauged with greater precision.

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Table 1. Definition and descriptive statistics of all variables

Variable names	*Explanation* [a]	*Obser-vations*	*Mean*	*Standard deviation*	*Maximum*	*Minimum*
	Independent variables:					
InsurCov	Insurers cover purchases of medicines in this pharmacy	113	.1946903	.3977258	1	0
RealAssets	Also runs conventional pharmacies	113	.1327434	.3408085	1	0
PharmAge	Years since the pharmacy is opened (not a dummy variable [b])	113	1.141593	1.231051	7	0
	Dependent variables:					
	Quality of service:					
QualIndex	Scores of principal components analysis of standardized *PrescRqd*, *FrgnSales*, *OtherPrd*, *Products* and *Generics* [b]	104	0.000000	1.846403	-1.315452	4.014492
PrescRqd	Requires the buyer to present a prescription, without relying fully on an internal questionnaire	113	.300885	.4606857	1	0
FrgnSales	Sells in foreign markets products requiring prescription	104	.7019231	.4596285	1	0
OtherPrd	Sells other products in addition to medicines	113	.1415929	.3501851	1	0
Products	Number of products sold [b]	113	34.69912	45.03013	100	1
Generics	Sells generic medicines	113	.1415929	.3501851	1	0
UrgntFee	Additional cost of express or overnight delivery service (in US dollars) [b]	65	17.24615	4.130794	26	7
	Information to users:					
InfoIndex	Scores of principal components analysis of standardized *PhoneLine*, *E-mail*, *AskPharm*, *PriceLis* and *PriceCom* [b]	113	0.000000	1.257515	-3.122688	3.548617
PhoneLine	Offers a telephone line to help in problems related to purchases and deliveries	113	.5221239	.5017353	1	0
E-mail	Offers an E-mail address for buyers to contact about purchases and deliveries	113	.9911504	.0940721	1	0
AskPharm	Offers a service for buyers to consult about the use of medicines, doses, etc.	113	.3451327	.4775292	1	0
PriceLis	Presents lists of its prices	113	.9557522	.2065612	1	0
PriceCom	Offers price comparisons with competitive pharmacies	113	.0619469	.2421329	1	0
	Third party quality certification:					
Certifcs	Sum of certifications (including *VIPPS*, *HON*, *VeriSign* and others; could take integer values zero to eight) [b, c]	113	.2831858	.6610196	3	0
VIPPS	Holds the VIPPS quality certification, created by the National Association of Boards of Pharmacy	113	.0884956	.2852794	1	0
HON	Follows the code of conduct of the foundation Health on the Net	113	.0530973	.2252264	1	0
VeriSign	Site registered as a VeriSign Secure Site Program	113	.079646	.2719504	1	0

Notes: [(a)] All variables are dummies that take values one when true, zero otherwise, unless those marked [(b)]. [(c)] In addition to VIPPS, HON and VeriSign, five other certifications are represented in the sample: NCPA, Hi-Ethics, TRUSTe, BBBOnLine and ePublicEye.

Table 2. Principal components analysis used to build the service quality index

Component	*Eigenvalue*	*Difference*	*Proportion*	*Cumulative*	
1	3.40920	2.66557	0.6818	0.6818	
2	0.74364	0.32318	0.1487	0.8306	
3	0.42046	0.07426	0.0841	0.9147	
4	0.34620	0.26570	0.0692	0.9839	
5	0.08050	.	0.0161	1.0000	
Eigenvectors					
Variable	*1*	*2*	*3*	*4*	*5*
PrescRqd	0.51322	0.06843	-0.07530	0.37672	0.76442
FrgnSale	-0.43557	0.31256	0.71138	0.43878	0.11829
OtherPrd	0.40149	-0.56575	0.66609	-0.27334	-0.01859
Products	0.49684	0.09502	0.00484	0.58785	-0.63130
Generics	0.37262	0.75400	0.21111	-0.49525	-0.05280
Scoring	*Coefficients*				
Variable	*1*				
PrescRqd	0.51322				
FrgnSale	-0.43557				
OtherPrd	0.40149				
Products	0.49684				
Generics	0.37262				

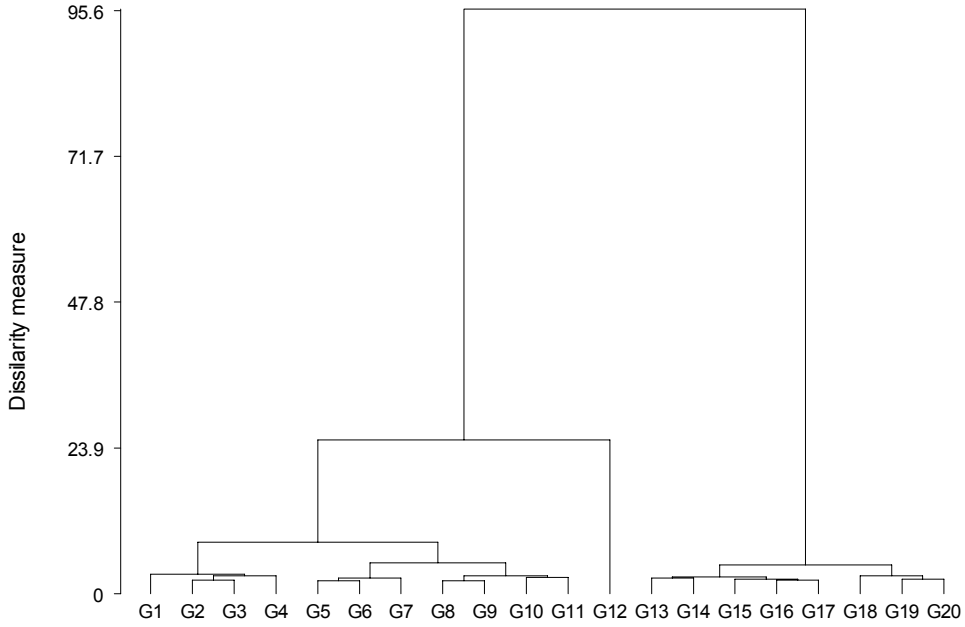
Note: Score based on unrotated principal components, 4 scorings not used.

Table 3. Principal components analysis used to build the information index

Component	*Eigenvalue*	*Difference*	*Proportion*	*Cumulative*	
1	1.58134	0.53393	0.3163	0.3163	
2	1.04741	0.08005	0.2095	0.5258	
3	0.96736	0.13214	0.1935	0.7192	
4	0.83522	0.26654	0.1670	0.8863	
5	0.56867	.	0.1137	1.0000	
Eigenvectors					
Variable	*1*	*2*	*3*	*4*	*5*
PhoneLine	0.62425	-0.07059	0.05812	0.35167	0.69157
Email	0.18742	0.49982	0.81065	-0.23052	-0.06907
AskPharm	0.59815	0.20443	-0.22856	0.32514	-0.66518
PriceLis	-0.45076	0.16375	0.24090	0.84340	-0.02553
PriceCom	-0.11924	0.82255	-0.47875	-0.07846	0.27172
Scoring	*Coefficients*				
Variable	*1*				
PhoneLine	0.62425				
Email	0.18742				
AskPharm	0.59815				
PriceLis	-0.45076				
PriceCom	-0.11924				

Note: Score based on unrotated principal components, 4 scorings not used.

Figure 1. Cluster dendrogram



Note: View limited to the top 20 branches.

Table 4. Characteristics and comparison of means of the two main clusters of online pharmacies

Variable	*Group of low quality pharmacies*			*Group of high quality pharmacies*			*Mean comparison*	
	Number	*Mean*	*Std. Dev.*	*Number*	*Mean*	*Std. Dev.*	*t test*	*P > |t|*
InsurCov	77	0	0	36	.6111111	.4944132	-7.4152	.0000
RealAssets	77	0	0	36	.4166667	.5	-5.000	.0000
PharmAge	77	.8571429	.8226127	36	1.75	1.679711	-3.0243	.0042
QualIndex	70	-1.171907	.3741161	34	2.412749	1.198849	-17.0367	.0000
PrescRqd	77	.012987	.1139606	36	.9166667	.280306	-18.6367	.0000
FrgnSales	70	.9	.3021661	34	.2941176	.4624973	6.9519	.0000
OtherPrd	77	0	0	36	.4444444	.5039526	-5.2915	.0000
Products	77	4.168831	4.894687	36	100	0	-171.8016	.0000
Generics	77	0	0	36	.4444444	.5039526	-5.2915	.0000
UrgntFee	44	18.70455	2.833188	21	14.19048	4.781412	4.0039	.0004
InfoIndex	77	-.5123301	.8651883	36	1.095817	1.273691	-6.8706	.0000
PhoneLine	77	.3766234	.4877165	36	.8333333	.3779645	-5.4365	.0000
Email	77	.987013	.1139606	36	1	0	-1.0000	.3205
AskPharm	77	.1428571	.3522217	36	.7777778	.421637	-7.8454	.0000
PriceCom	77	.0649351	.2480271	36	.0555556	.2323107	0.1957	.8454
PriceLis	77	.987013	.1139606	36	.8888889	.3187276	1.7943	.0804
Certifcs	77	.025974	.1601008	36	.8333333	.9411239	-5.1127	.0000
VIPPS	77	0	0	36	.2777778	.4542568	-3.6690	.0008
HON	77	0	0	36	.1666667	.3779645	-2.6458	.0121
VeriSign	77	.012987	.1139606	36	.2222222	.421637	-2.9279	.0058

Note: Means are compared assuming unequal variances and using Welch formula (1947).

Table 5. Dependent variables which are fully determined by some independent variables ('structural zeroes')

Dependent variables			*Independent dummy variables*			
Variable name	*Observations*	*Values*	*InsurCov =*		*RealAssets =*	
			= 0	*= 1*	*= 0*	*= 1*
PrescReq	113	0	79	0	79	0
		1	12	22*	19	15*
PhoneLine	113	0	54	0	52	2
		1	37	22*	46	13
E-mail	113	0	1	0	1	0
		1	90	22*	97	15*
AskPharm	113	0	74	0	72	2
		1	17	22*	26	13
VIPPS	113	0	91*	12	90	13
		1	0	10	8	2
HON	113	0	91*	16	93	14
		1	0	6	5	1
Observations	113		91	22	98	15

Note: (*) According to the sample, the value of the independent variable fully determines the dependent variable.

Table 6. Determinants of quality attributes of online pharmacies

	Dependent variables:															
	Service quality						*Information channels and price information provided*						*Third party certification*			
	Service Quality index	*Quality dimensions included in online pharmacies' service quality index*					*Express delivery*	*Information index*	*Main specific information channels*		*Price information provided online*		*Total number of certificates*	*Main specific certifications*		
	QualIndex	*PrescRqd*	*FrgnSales*	*OtherPrd*	*Products*	*Generics*	*UrgntFee*	*InfoIndex*	*PhoneLine*	*AskPharm*	*PriceCom*	*PriceLis*	*Certifcs*	*VIPPS*	*HON*	*VeriSign*
	(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(7)*	*(8)*	*(9)*	*(10)*	*(11)*	*(12)*	*(13)*	*(14)*	*(15)*	*(16)*
Independent variables:																
InsurCov	2.798***	+*****(b)	-4.408***	6.814***	60.749***	0.874	-4.958***	1.710***	+*****(c)	+*****(c)	0.004	-2.006	4.801***	+*****(d)	+*****(d)	2.780***
	(0.263)		(1.110)	(2.298)	(7.324)	(0.685)	(1.199)	(0.249)			(1.301)	(1.350)	(0.861)			(0.906)
RealAssets	1.782***	+*****(b)	-2.871***	0.842	44.477***	2.170***	1.430	0.838***	1.070	2.336**	0.320	-2.016*	-1.196	-1.715*	-1.567	0.182
	(0.294)		(0.963)	(0.977)	(8.313)	(0.701)	(2.032)	(0.249)	(0.907)	(0.932)	(1.251)	(1.120)	(0.845)	(1.004)	(1.223)	(0.889)
PharmAge	0.311***	0.761**	-0.352	1.236**	6.477***	0.311	0.334	0.052	0.192	0.230	-0.718	1.160	0.383*	0.015	0.075	0.387
	(0.078)	(0.333)	(0.233)	(0.488)	(2.180)	(0.208)	(0.357)	(0.074)	(0.190)	(0.216)	(0.574)	(0.905)	(0.229)	(0.367)	(0.366)	(0.269)
Constant	-1.145***	-3.616***	2.586***	-8.250***	9.573***	-3.018***	17.871***	-0.503***	-0.641**	-1.953***	-2.173***	3.465***		0.440	-0.621	-4.331***
	(0.132)	(0.707)	(0.490)	(2.826)	(3.638)	(0.520)	(0.653)	(0.124)	(0.291)	(0.390)	(0.522)	(0.828)		(0.927)	(0.939)	(0.882)
Observations	104	85	104	113	113	113	65	113	91	91	113	113	113	22	22	113
R^2	0.74				0.64		0.22	0.46								
Pseudo R^2		0.15	0.50	0.71		0.22			0.02	0.10	0.05	0.24	0.42	0.11	0.09	0.29

Notes: [(a)] Logit regressions except OLS in models (1), (5), (7) and (8) and ordered logit (13). [(b)] The variables *InsurCov* and *RealAssets* are dropped due to estimability caused by structural zeroes. As a consequence, only the 85 observations with *InsurCov* = 0 and *RealAssets* = 0 are considered. [(c)] The variable *InsurCov* dropped due to estimability—only the 91 observations with *InsurCov* = 0 are considered. [(d)] The variable *InsurCov* dropped due to estimability—only the 22 observations with *InsurCov* = 1 are considered. [(e)] Standard errors in parentheses. [(f)] ***, **, * = Statistically significant at the 99%, 95% and 90% confidence level. ***** = Structural zeroes.

Table 7. Basic attributes of services provided by online pharmacies
(estimation using interactive age variables)

	Dependent variables						
	Service quality		*Information provided*		*Third party certification*		
	QualIndex	*QualIndex*	*InfoIndex*	*InfoIndex*	*Certifcs*	*Certifcs*	*Certifcs*
	(1)	*(2)*	*(6)*	*(7)*	*(3)*	*(4)*	*(5)*
Independent variables:							
InsurCov	2.796***	2.745***	1.988***	1.751***	7.963***	8.095***	7.978***
	(0.423)	(0.261)	(0.398)	(0.242)	(1.565)	(1.560)	(1.523)
RealAssets	2.385***	2.386***	1.269***	0.839***	0.082	-2.080**	
	(0.431)	(0.429)	(0.415)	(0.282)	(2.032)	(0.933)	
PharmAge	0.381***	0.374***	0.141		0.948***	0.908***	0.948***
	(0.096)	(0.084)	(0.091)		(0.300)	(0.289)	(0.299)
InsurCov	-0.029		-0.189		-1.315***	-1.375***	-1.319***
**PharmAge*	(0.191)		(0.184)		(0.471)	(0.468)	(0.458)
RealAssets	-0.407*	-0.402*	-0.327		-1.398		-1.353**
**PharmAge*	(0.214)	(0.210)	(0.209)		(1.259)		(0.587)
Constant	-1.217***	-1.210***	-0.588***	-0.452***			
	(0.142)	(0.135)	(0.133)	(0.100)			
Observations	104	104	113	113	113	113	113
R^2	0.75	0.75	0.48	0.46			
Pseudo R^2					0.49	0.48	0.49

Notes: OLS regressions except ordered logit in models (3) to (5). Standard errors in parentheses.
***, **, * = Statistically significant at the 99%, 95% and 90% confidence level.

Table 8. Comparison between reduced-form models and structural equations

	Individual OLS estimations			*System of simultaneous equations (three-stage estimation)*		
	Dependent variables:					
	QualIndex	*Certifcs*	*InsurCov*	*QualIndex*	*Certifcs*	*InsurCov*
	(1)	(2)	(3)	(4)	(5)	(6)
InsurCov	2.798***	0.827***		3.331***	1.076*	
	(0.263)	(0.166)		(0.502)	(0.570)	
RealAssets	1.782***	-0.596***		1.563***	-0.530**	
	(0.294)	(0.147)		(0.343)	(0.231)	
PharmAge	0.311***			0.272***		
	(0.078)			(0.084)		
QualIndex		0.160***	0.089***		0.104	0.076***
		(0.040)	(0.017)		(0.133)	(0.028)
Certifcs			0.222***			0.121
			(0.043)			(0.185)
InfoIndex			0.063***			0.099**
			(0.022)			(0.050)
Constant	-1.145***	0.190***	0.134***	-1.173***	0.134	0.162***
	(0.132)	(0.057)	(0.024)	(0.134)	(0.137)	(0.055)
Observations	104	104	104	104	104	104
"R^2"	0.74	0.62	0.72	0.73	0.61	0.69

Notes: Table entries in columns (1) to (3) report OLS coefficients for column variables regressed onto row variables. Entries in columns (4) to (6) report coefficients of a system of simultaneous structural equations estimated thorough three-stage regression. Standard errors in parentheses. ***,**,* = Statistically significant at the 99%, 95% and 90% confidence level.