Intern. J. of Research in Marketing 28 (2011) 295–308

Contents lists available at SciVerse ScienceDirect

Intern. J. of Research in Marketing

journal homepage: www.elsevier.com/locate/ijresmar

The global entry of new pharmaceuticals: A joint investigation of launch window and price ☆

Isabel Verniers [a,b,*], Stefan Stremersch [a,c], Christophe Croux [d]

[a] Erasmus School of Economics, Erasmus University Rotterdam, Burgemeester Oudlaan 50, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands
[b] Faculty of Economics and Business Administration, Ghent University, Tweekerkenstraat 2, 9000 Gent, Belgium
[c] IESE Business School, Universidad de Navarra, Avenida Pearson 21, 08034 Barcelona, Spain
[d] Faculty of Business and Economics, Catholic University of Leuven, Naamsestraat 69, 3000 Leuven, Belgium

ARTICLE INFO

Article history:
First received in 10, September 2009 and was under review for 5 months
Available online 5 October 2011

Area Editor: Harald Van Heerde

Keywords:
Entry timing
International new product launch
Launch price
Launch window
Pharmaceutical
Regulation

ABSTRACT

Research on the launch of new products in the international realm is scarce. The present paper is the first to document how launch window (the difference, in months, between the first worldwide launch and the subsequent launch in a specific country) and launch price are interrelated and how regulation influences both the launch window and launch price. The research context is the global (50 countries worldwide) launch of 58 new ethical drugs across 29 therapeutic areas. We show that the fastest launch occurs when the launch price is moderately high and the highest launch price occurs at a launch window of 85 months. We find that the health regulator acts strategically in that the extent to which it delays the launch of a new drug increases with the price of the new drug. We also find that overall, regulation increases the launch window, except for patent protection. Surprisingly, regulation does not directly impact launch price. The descriptive information on average launch window and launch price and the interconnection between launch window and launch price allow managers in ethical drug companies to make more informed decisions about international market entry. This study also provides public policy analysts with more quantitative evidence on launch window and launch price across a broad sample of countries and drug therapeutic categories.

1. Introduction

Marketing scholars have long shown a strong interest in the launch of innovations (for examples, see Golder and Tellis, 1993; Shankar, Carpenter, and Krishnamurthi, 1998, 1999). However, research on the launch of new products in the international realm is scarce. The rare exceptions focus on the choice between a waterfall and a sprinkler strategy for international entry (Kalish, Mahajan, and Muller, 1995; Libai, Muller, and Peres, 2005; Stremersch and Tellis, 2004; Tellis, Stremersch, and Yin, 2003) and on whether products diffuse more quickly in lead countries (in which the product was introduced first) than in lag countries (in which the product was introduced later) (for example, Dekimpe, Parker, and Sarvary, 2000; Eliashberg and Helsen, 1996).

The lack of attention to international product entry decisions sharply contrasts with the high relevance that international launch time decisions have for today's globally operating firms. The commercialization or launch phase is an important phase for a company (Hultink, Griffin, Robben, and Hart, 1998) in which it makes decisions on launch time and price, both of which have large implications for future profits (Gregson, Sparrowhawk, Mauskopf, and Paul, 2005; Hultink et al., 1998; Urban and Hauser, 1993). In essence, launch time and price are important determinants of the evolution and distribution of cash flows across time and countries.

In the pharmaceutical market – the context of the present paper – regulatory bodies such as the FDA (Food and Drug Administration) in the US and the EMEA (European Medicines Evaluation Agency; the European counterpart of the FDA) review and approve a new drug's effectiveness and safety. After scientific approval, the firm negotiates with local health regulators for market access, typically at the country level. These parties must jointly determine launch time and launch price, even though they may have opposite interests. Ethical drug firms (firms that sell prescription drugs) aim to recoup R&D investments through early access (i.e., a long life cycle under patent protection) and a high price, both of which have an important impact on ethical drug companies' bottom line (Boulding & Christen, 2003; Danzon, Wang, and Wang, 2005; Wagner and McCarthy, 2004). Health regulators wish to contain health costs while making new life-enhancing and life-saving drugs available to the population (Danzon et al., 2005). To contain their health budgets, many countries have introduced some form of regulation that restricts a firm from setting prices freely. For instance, Spain has set a threshold (12–18% of allowable cost) that regulates the profit margins

☆ The authors acknowledge the data support of IMS Health and the intellectual stimulation of Servaas Buijs in particular.

* Corresponding author at: Erasmus School of Economics, Erasmus University Rotterdam, The Netherlands. Tel.: +31 10 408.13.11; fax: +31 10 408.91.69.
E-mail address: verniers@ese.eur.nl (I. Verniers).

0167-8116/$ – see front matter © 2011 Elsevier B.V. All rights reserved.
doi:10.1016/j.ijresmar.2011.05.008

that ethical drug firms can make, which may put downward pressure on prices in Spain and make manufacturers less keen to enter Spain promptly (Kanavos, 2001).

Prior studies (Danzon et al., 2005; Kyle, 2006, 2007; Lanjouw, 2005) have examined launch timing without accounting for launch price. Other authors have studied launch price without accounting for launch timing (e.g., Berndt, 2000; Danzon and Chao, 2000a; Danzon and Furukawa, 2003, 2006; Danzon and Kim, 1998; Huttin, 1999). The present paper examines how launch timing and launch price interrelate and how regulation affects both decisions. In terms of launch timing, we focus on launch window, which is the difference in months between the first worldwide launch and the subsequent launch in a specific country. We gathered monthly launch windows and launch prices for 58 new drugs across 29 different therapeutic categories launched by ethical drug companies in 50 developed and developing (see also Burgess and Steenkamp, 2006) countries worldwide, yielding a rich dataset on both the drug and country levels. We simultaneously estimate a launch window equation and a launch price equation, capturing the endogeneity of these decisions.

We find that launch price has a U-shaped effect on launch window, whereas launch window has an inverted U-shaped effect on launch price. In our sample, the fastest launch occurs when the launch price is moderately high, and the highest price occurs at a launch window of about 85 months. We also find that health regulators act strategically, as the launch window increases with the price of the new drug. Overall, we find that regulation lengthens the launch window. Contrary to our expectations, we do not find that regulation directly influences launch prices. Interestingly, such regulations, rather than affecting the launch price per se, may serve to reduce prices more quickly over the life cycle; Stremersch & Lemmens 2009 provide anecdotal evidence for this claim based on the price pattern they observe in Belgium, Canada, Germany, Switzerland, the UK, and the US. Our novel findings are based on a large sample of new pharmaceutical drugs and have high relevance for both firms and regulators. Within the bounds of the data, our model can provide insights into hypothetical situations such as how a further delay in the entry of a new drug may affect launch price. The descriptive information on average launch window and launch price and the interconnection between launch window and launch price allow managers in ethical drug companies to make more informed decisions about international market entry. This study also provides public policy analysts with more quantitative evidence regarding launch window and price for a broad sample of countries and therapeutic categories.

2. Theoretical background

This section first reviews the literature on international launch windows and launch prices in both marketing and economics. Then, we develop hypotheses on the interrelationship between launch window and launch price and on the effect of regulation on launch window and launch price. We end with a discussion of the other variables that may affect launch window and launch price, which we control for in our estimation.

2.1. Past literature on international launch window and price

Table 1 summarizes prior studies on international launches of new products[1] and international pricing published in economics and marketing. From Table 1, we learn that previous studies have not considered the interrelationship between launch window and launch price. Prior research on international launch has focused on identifying determinants of launch windows. Prior research on international pricing has primarily focused on bilateral price comparisons but has only examined the determinants of such differences in a few cases. In such papers, scholars have examined the influence of competition or a firm's country of origin on international pricing differences. We also learn from Table 1 that our study is one of the most comprehensive ever on this topic given the number of new products and countries studied and the richness of the covariate set included in our model.

2.2. The interrelationship of launch window and launch price

In the pharmaceutical industry, launch window and launch price are the result of an undisclosed negotiation process between health regulators (e.g., governments and government institutes) and ethical drug companies (Danzon et al., 2005; Garattini and Ghislandi, 2007). The launch window and launch price are important to ethical drug companies because they affect the evolution and distribution of cash flows over time and across countries. This incoming cash flow for firms corresponds to healthcare spending for health regulators.

In addition to containing healthcare spending, health regulators may also aim to improve the population's access to state-of-the-art healthcare. The combination of these two objectives presents health regulators with a formidable challenge because new drugs promise greater medical benefits, but typically at a higher price than prior alternatives. Thus, from both a regulator's and a firm's perspective, launch price and launch window may be interrelated.

The relationship between launch window and launch price has three distinct aspects: (1) the causal effect of launch price on launch window; (2) the causal effect of launch window on launch price; and (3) the joint determination of both. Next, we develop hypotheses on the first two aspects; we will control for the simultaneity of the launch window and launch price decisions in our empirical tests.

We first consider the effect that launch price may have on launch window. If the launch price of a new drug is high, the drug represents, ceteris paribus, a more attractive market opportunity for the ethical drug company than when the launch price of a new drug is low (Jack, 2007, April 18), making the ethical drug company more keen to launch quickly to maximize the net present value of its future revenue streams (Gregson et al., 2005). This argument is in line with Giaccotto, Santerre, & Vernon (2005) and Ridley (2007), who documented that low prices may be detrimental to the worldwide launch of new drugs. Ethical drug firms may also be concerned that launching quickly in low-price countries may drive down the drug's price in high-price countries in the future (Gregson et al., 2005).

Health regulators, ceteris paribus, may be increasingly negatively disposed to the launch of a new drug as it becomes more expensive, which is the result of concerns over increasing healthcare budgets, of which pharmaceutical drug expenses are a substantial part (Cohen, Faden, Predaris, and Young, 2007; Gregson et al., 2005). Healthcare budgets worldwide are under pressure because of aging populations in many developed countries and growing populations in many developing countries. The increased budget pressure has lowered health regulators' aspirations to provide fast market access to expensive new drugs (Comanor and Schweitzer, 2007). Health regulators may soften the impact of expensive drugs on their budget by delaying their entry, either explicitly in the price negotiation, e.g., by not promptly agreeing to the manufacturer's proposed price (Danzon et al., 2005), or by increasing the administrative approval burden for expensive medication.

Given the opposing interests of firms and regulators, we propose a curvilinear relationship between launch price and launch window in which launch occurs most rapidly at moderate launch prices. The reason for this prediction is that a very low launch price may be unacceptable to the firm, whereas a very high price may be unacceptable to the regulator. In both cases, either the firm or the regulator will seek to delay launch to put pressure on the other party in the negotiation. Both parties will only align on a quick launch if the price is

[1] We exclude studies on within-country order of entry and studies on firm entry from this review.

Table 1
Overview of prior studies on international launch window and pricing and a comparison with the present study.

Reference	Dependent variable	Focal independent variables	Launch window modeled?	Launch price modeled?	Number of geographic markets	Number of products	Product markets	Key findings
Bolton & Myers (2003)	Price sensitivity	Service quality, type, and support	No	No	7	1	Software systems	Service quality, type, and support have a significant, positive influence on price elasticities. This effect depends on national and regional variables.
Chintagunta & Desiraju (2005)	Price level	Home country of firm	No	No	5	3	Pharmaceuticals	Firms charge a higher price for drugs in their home country. These firms behave more aggressively toward their competitors in their home market.
Danzon & Chao (2000a)	Bilateral drug price indexes	Competition	No	No	7	171	Pharmaceuticals	Within-country price competition influences differences in prices across countries.
Danzon & Furukawa (2003)	Bilateral drug price indexes	Income Exchange rates On-patent versus generic drug	No	No	8	249	Pharmaceuticals	Prices in Japan and the US are higher than prices in other countries.
Danzon et al. (2005)	Launch window	Market size Competition Firm characteristics	Yes	No	25	85	Pharmaceuticals	Countries with lower expected prices or smaller expected market size have longer launch windows (i.e., longer launch delays).
Dawar & Parker (1994)	Relative and absolute importance of price as a quality signal	National (workforce, culture, etc.) and individual characteristics	No	No	38	1	Consumer electronics	Price as a quality signal does not depend on culture but is likely to depend on individual characteristics.
Ekelund & Persson (2003)	Price levels	Competition	No	Yes	1	246	Pharmaceuticals	Price regulation in Sweden discourages price competition.
Goldberg & Verboven (2001)	Price levels	Firm characteristics (country of origin, costs, import quota constraints)	No	No	5	Approx. 150	Cars	Higher prices are partially attributable to a preference for domestic brands.
Kalish et al. (1995)	Launch window	Competition, size and growth of foreign market, fixed cost of entry, product life cycle, innovativeness	Yes	No	No empirical data	No empirical data	No empirical data	A waterfall strategy is preferred under certain conditions, such as high fixed entry costs and low competitive pressure.
Kyle (2006)	Launch window	Firm characteristics	Yes	No	7	1482	Pharmaceuticals	A new drug is launched more quickly in countries where the company has its headquarters.
Kyle (2007)	Launch window	Regulation	Yes	No	25	1444	Pharmaceuticals	Countries with price controls show longer launch windows.
Lu & Comanor (1998)	Price levels	Competition	No	Yes	1	144	Pharmaceuticals	The number of branded substitutes has a significant, negative effect on launch prices.
Rojas (2009)	Price levels	Company type	No	No	6	641	Pharmaceuticals	Significant differences in the prices of identical drugs exist across Central American countries.
This study	Launch window and launch price	Regulation (economy, demography, competition, culture, drug, firm)	Yes	Yes	50	58	Pharmaceuticals	Launch window has an inverted U-shaped effect on launch price, whereas launch price has a U-shaped effect on launch window. We also find that, overall, regulation lengthens the launch window, except for patent protection. Surprisingly, regulation does not directly impact launch price.

moderate. This expectation is consistent with earlier findings in the negotiation literature that challenging yet attainable goals lead to an integrative solution for both parties involved (McAlister, Bazerman, and Fader, 1986).

In sum, we hypothesize:

H1. Launch price has a U-shaped effect on launch window.

Next, we consider the effect of launch window on launch price. New drugs typically receive a fixed patent protection period of 20 years from initial filing for approval of a new drug (Danzon et al., 2005; DiMasi, Hansen, and Grabowski, 2003; Kyle, 2006). After this initial filing, it typically takes between 8 and 12 years for a drug to be developed and clinically tested before it is approved for commercial use by organizations such as EMEA in Europe and the FDA in the US. After approval, the applicant has a monopoly on marketing the approved substance for the remaining years of the patent life cycle, 11 years on average (Grabowski and Kyle, 2007). An ethical drug firm aims to recuperate its R&D expenditures on discovery and the different stages of clinical development and testing and its market entry expenditures on local cost-effectiveness studies, conferences with key opinion leaders and physician detailing, among others, over the life cycle of the drug. An ethical drug firm generates the dominant share of its profits when the drug is still under patent protection and has no bioequivalent competition (Lu and Comanor, 1998). Pharmaceutical companies operating in an international context launch at different times in different countries because of differences in approval and administrative procedures or because of

differences in countries' market attractiveness. The longer the launch window becomes (e.g., because of long administrative procedures), the less time that the drug remains under patent protection in the global context, and the more the firm will insist on a higher price to make up for the lost time under exclusivity.

The health regulators may react to the launch window in the opposite way. As time passes, more information on the drug spreads around the world, and the drug loses its novelty. Generic alternatives become a more prominent benchmark as patent expiry nears (Morton, 1999), and a larger volume of independent studies in foreign populations outside of a clinical setting (i.e., when the drug is commercially available on foreign markets) may call into question the drug's efficacy (e.g., duloxetine) or raise important safety issues (e.g., Vioxx) (see Sood and Stremersch, 2010). Thus, the health regulator's willingness to pay for the drug may decrease over time.

Combining both arguments, we propose an inverted U-shaped effect of launch window and launch price in which launch price is highest at moderate launch windows. At moderate launch windows, the firm can still make money under patent protection if the price is high enough to make up for local market entry expenditures. At very short launch windows, the firm will accept a lower launch price more easily because the drug enjoys a full life under patent protection, so the firm begins recuperating R&D expenditures and gains resources for international market access immediately. At very long launch windows, the health regulator's reference point will be based on generic drug prices. The firm itself may also already be in "generic" mode as its drug nears patent expiration globally and it prepares for generic competition. Therefore, at very long launch windows, both entities will align more easily at a relatively low launch price as a prelude to generic competition.

We hypothesize:

H2. Launch window has an inverted U-shaped effect on launch price.

2.3. The effects of regulation on launch window and launch price

To control pharmaceutical spending, many countries apply various forms of regulatory restrictions, which may affect launch window and launch price (Abbott, 1995; Ekelund and Persson, 2003; Kanavos, 2001; Mossialos, Mrazek, and Walley, 2004). We discuss each of these regulatory restrictions and their hypothesized effects on launch window and launch price.

2.3.1. Ex-manufacturer price regulation

The first regulatory requirement that we consider is the presence of ex-manufacturer price control. Ex-manufacturer price control caps the ex-manufacturer price (the price charged by the manufacturer to the wholesaler) of a pharmaceutical product. A country's public health administration determines a maximum price or reservation price that a manufacturer can charge (Danzon et al., 2005). Belgium, Greece and Portugal are examples of countries with strict ex-manufacturer price regulation. Ex-manufacturer price control may slow market access because it often lengthens the price negotiation process between regulator and manufacturer. Heuer, Mejer, & Neuhaus (2007) and Kyle (2007) found, for a limited sample of countries, that ex-manufacturer price control delays new drug launch. Furthermore, Mossialos et al. (2004) state, albeit without an empirical test, that countries with ex-manufacturer price control are more likely to have lower introductory prices than countries without such control. Ekelund & Persson (2003) and Lu & Comanor (1998) show that introductory prices are not lower in countries with a price cap regulation than in countries without a price cap regulation. Danzon & Chao (2000b) show across a sample of 7 countries that prices decline more with molecule age in countries that apply ex-manufacturer price control than in countries that do not apply this control. Although the evidence is mixed, we expect launch prices to be lower in countries that apply this price control system than in countries that do not.

We hypothesize:

H3. New drugs are launched (a) later and (b) at a lower price in countries with ex-manufacturer price regulation than in countries without ex-manufacturer price regulation.

2.3.2. Profit regulation

Public policy administrators may also influence the general price levels of drugs more indirectly by restricting the profits that ethical drug firms can obtain. In such a regulatory context, drug companies are free to set their own prices but cannot exceed a predetermined profit ceiling (Jacobzone, 2000). The UK is a well-known example of a country that applies profit control regulation, in which the government negotiates with individual ethical drug companies on the amount of profit they can make (Borrell, 1999). Although scholars have not examined the direct effect of profit control on launch window, we argue that it may slow market access. In general, the profit contribution of new products is considered to be large (Chandy and Tellis, 1998). New drugs typically enhance ethical drug firms' profitability (Wuyts, Dutta, and Stremersch, 2004), so profit controls cap firms' overall profit margins. Therefore, ceteris paribus, ethical drug firms will prefer to sustain mature drugs over launching newly developed drugs on markets with profit controls (Rapp and Lloyd, 1994).

The agreed-upon return-on-capital threshold of the profit regulation provides incentives for manufacturers to set their prices so that profits do not exceed this threshold. Exceeding these profit rates can lead to a penalty that forces companies to lower their prices (Novartis, 2004, June 21). Therefore, we expect that companies may set lower launch prices for their newly developed drugs in countries that control profit.

Therefore, we hypothesize:

H4. New drugs are launched (a) later and (b) at a lower price in countries with profit regulation than in countries without profit regulation.

2.3.3. Cross-country reference pricing

The third regulatory restriction that we consider is whether the regulator demands information from the manufacturer on drug prices in other countries. Under this regulation, health regulators require companies to supply information on prices in selected foreign countries for the drugs that they want to launch and then cap prices based on that information (Dukes, Haaijer-Ruskamp, de Jonckheere, and Rietveld, 2003). A good example is Austria, where the government asks companies for notification on their ex-manufacturer prices in similar countries.

Although the aim of this regulation is to provide another mechanism for capping drug prices, the comparison between countries can create industry concern that a low introductory price will spill over to other countries. Therefore, cross-country reference pricing may show counterintuitive effects (Hunter 2005). First, when a country applies cross-country reference pricing, firms will try to gain market access as early as possible to minimize the number of reference countries. Second, cross-country reference pricing may push prices upward rather than downward. Typically, regulators that seek early drug access are more willing to agree to higher prices. Thus, the likelihood of a reference country having a high price rather than a low price is higher early in the life cycle than it is later on. Consequently, the reference set of a country is likely to contain a greater number of countries with high prices than countries with low prices early in the life cycle as compared to late in the life cycle.

H5. New drugs will be introduced (a) earlier and (b) at a higher price in countries that have a cross-country reference pricing mechanism than in countries that do not have a cross-country reference pricing mechanism.

2.3.4. Therapeutic reference pricing

Therapeutic reference pricing refers to the presence (or absence) of a system to classify products into clusters based on therapeutic similarity (Danzon and Furukawa, 2003). Health regulators set a reference price for each cluster based on a low-priced product. If the manufacturer's price is set above this reference level, the patient must pay a surcharge. Therapeutic reference pricing is different from ex-manufacturer price control in that it concerns the reimbursement level of a drug rather than its price (Dukes et al., 2003). Germany, the Netherlands and New Zealand are especially known for their therapeutic reference pricing systems.

Danzon & Furukawa (2003) claim that therapeutic reference pricing causes price pressure. The reason is that drugs that cost more than the reference price require substantial co-pay by the patient, making these drugs less attractive. Danzon & Ketcham (2003) show that more stringent systems of therapeutic reference pricing are associated with lower prices as compared to less stringent systems of therapeutic reference pricing.

Typically, therapeutic referencing also delays launch because the administrative procedure requires an examination of therapeutic similarities, delaying market access.

H6. New drugs will be introduced (a) later and (b) at a lower price in countries that apply a therapeutic reference pricing system as compared to countries that do not apply a therapeutic reference pricing system.

2.3.5. Pharmaco-economic evidence

Regulators may require pharmaceutical firms to provide pharmaco-economic evidence in support of their new drug (Dickson, Hurst, and Jacobzone, 2003). Based on this evidence, regulators try to establish fair prices through calculations where the costs of a drug are weighed against its direct and indirect benefits. Pharmaco-economic evidence presents the cost effectiveness of a treatment with a new drug as the ratio of the cost of treatment (including the drug price, hospital stays, surgery, and so on) to relevant measures of its effect (Garber and Phelps, 1997). Australia has one of the most developed systems using pharmaco-economic evidence (Dukes et al., 2003).

This requirement demands, in addition to the clinical evidence required to gain therapeutic approval from institutes such as the FDA or EMEA, evidence on the cost effectiveness of the drug in the *local* population that must be submitted according to complicated administrative procedures. This requirement often causes a delay in market access in a manner similar to therapeutic reference pricing (Wilking and Jönsson 2005). On the positive side, it also makes the market access procedure more evidence based (Stremersch and Van Dyck, 2009), which may effectively yield higher prices because of stronger clinical evidence.

H7. New drugs will be introduced (a) later and (b) at a higher price in countries that require pharmaco-economic evidence as compared to countries that do not require pharmaco-economic evidence.

2.3.6. Patent protection

Ethical drug companies find countries that strictly enforce patent protection to be more attractive than countries that do not strictly enforce patent protection because strict enforcement protects them from bio-equivalent price competition. Thus, stronger patent protection may encourage ethical drug companies to enter relatively early because their period of exclusivity after entrance is well protected. Furthermore, stronger patent protection may impose a downward pressure on launch prices because pharmaceutical companies can be more lenient on prices if there is sufficient time left under patent protection to recuperate R&D expenditures.

H8. New drugs will be introduced (a) earlier and (b) at a lower price in countries with more patent protection as compared to countries with less patent protection.

2.4. Other variables[2]

We control for market size of a country by including *population size* and *health expenditures per capita* in our model. Firms may be more prompt in their attempts to access large markets, thus shortening the launch window, but they will be less willing to compromise on launch price because accepting a low price in large markets has large (negative) effects on anticipated profits. Additionally, health regulators in large markets may be more prompt in allowing new drugs to market because the number of affected people is larger than in small markets. Firms may be more eager to launch in countries with high health expenditures per capita as these countries may have a more favorable attitude towards new drugs. However, higher health expenditures per capita could lower health regulators' aspirations to provide quick market access to new drugs (Comanor and Schweitzer, 2007) or to allow high prices because they feel higher budget pressure.

A second set of variables operationalizes a country's *national culture*, for which we use the four dimensions identified by Hofstede (1980 and 2001): *uncertainty avoidance*, *masculinity*, *individualism*, and *power distance*. Hofstede (2001) has argued that members of uncertainty-avoidant cultures show lower subjective health perceptions as compared to members of cultures low in uncertainty avoidance (Hofstede, 2001). Low subjective health perceptions may encourage health regulators to allow prompt access to new drugs and to be less price sensitive. Thus, we expect the launch window to be shorter and the launch price to be higher in uncertainty-avoidant countries as compared to countries that are low in uncertainty avoidance.

Masculine societies are characterized to a greater extent by assertiveness versus nurturance (Hofstede, 2001). Societies low in nurturance may perceive a lower need for medical care unless it is really necessary (Weber, Roberts, and McDougall, 2000). Health regulators in masculine societies may be more resistant to allowing prompt market access and may show a lower willingness to pay as compared to health regulators in feminine societies, especially for drugs that treat non-life-threatening diseases. Thus, we expect that, on average, the launch window is longer and the launch price is lower in masculine countries as compared to feminine countries.

Hofstede (2001) has argued that members of a culture that is high in individualism show greater satisfaction toward health care and spend more money on healthcare as compared to cultures that are low in individualism. Therefore, we expect a shorter launch window and a higher launch price in individualistic countries as compared to collectivist countries.

Members of a culture that is high in power distance perceive a higher degree of inequality in power between themselves and the more powerful party. These societies are often more bureaucratic (Hofstede, 2001). Therefore, we expect the launch window to be longer in societies that are high in power distance as compared to countries that are low in power distance. We have no ex ante expectation about the influence of power distance on launch price.

[2] Although unit sales will also affect the evolution and distribution of cash flows across time and countries, we consider its inclusion to be beyond the scope of our study. Its full inclusion would require a model with a much higher complexity that accounts for adoption timing, repeat sales and compliance of patients. Although this lower complexity comes at the threat of omitted variable bias, it seems reasonable to assume that unit sales are not sensitive to introduction timing in the context of new pharmaceuticals (as documented empirically by Stremersch and Lemmens, 2009), nor is it likely that early unit sales are sensitive to launch price (physicians typically first prescribe a new treatment to patients who were impossible or difficult to treat with previously available alternatives, which makes early market adoption a function of drug efficacy and little else, as argued in Vakratsas and Kolsarici, 2008).

Third, we control for the *competition* a drug faces within a category. The more competing drugs there are in a category, the higher the pressure on the firm to launch quickly in order to secure adoption from newly diagnosed patients. However, the regulator faces less pressure to grant market access. Strong competition also provides the health regulator with bargaining power to obtain a low price (Ekelund and Persson, 2003; Lu and Comanor, 1998). Thus, the effect of competition on the launch window is unclear, and we expect the effect of competition on launch price to be negative. The latter expectation is consistent with Chintagunta & Desiraju (2005), who found that prices of drugs across 5 markets are lower when there is more competition.

Fourth, we control for a *home country* effect on both launch window and launch price. Ethical drug companies' greater familiarity with the home market's therapeutic needs or health regulators' favoritism toward these ethical drug companies may lead to a faster launch (Kyle, 2006) and a higher launch price (Wagner and McCarthy, 2004).

Fifth, we control for two additional covariates that we expect to influence launch window but not launch price (*Summer* and *EMEA*). Because approvals show a seasonal pattern around summer holidays (Sietsema, 2006), we expect an influence of *Summer* on the launch window. Second, although market access and price negotiations take place at the country level, the drug approval process in Europe is centralized. Given that the launch window (and not launch price) is co-determined by the scientific approval date of a new drug, EMEA member states will show greater similarity in their launch windows than will countries that are not members of EMEA. We expect launch windows in EMEA countries to be shorter than those in non-EMEA countries because of differences in administrative efficiencies. We do not expect an influence of EMEA membership on launch price because prices are set at the country level. The existence of parallel trade shows that the centralization of the drug approval process in the EMEA zone has not led to uniform prices (Danzon, 1998). We also control for two additional covariates that we expect to influence launch price but not launch window (*daily dosage* and *inflation rate*). We add these two variables to avoid biases in the measure of launch price. The launch price of a drug in grams may be influenced by the drug's defined *daily dosage* in grams. The launch price of a drug of which a patient needs a low daily dosage may be higher than the launch price of a drug of which a patient needs a high daily dosage. The reason is that health regulators and manufacturers negotiate a drug's price based upon the total therapy cost, irrespective of the dosage, because of the low variable (i.e., manufacturing) costs of the active ingredient in a drug. We also control for the *inflation rate* to make launch prices comparable across countries and time.

Finally, we include *therapeutic category* dummy variables. The inclusion of these fixed category effects is in line with previous research on drug launch windows (Danzon et al., 2005; Kyle, 2007; Lanjouw, 2005). Gregson et al. (2005) acknowledge that a country's evaluation of the therapeutic category's importance affects both the launch window and price of a new drug in that therapeutic category. For example, the importance of the erectile dysfunction drug category (or other lifestyle drugs) may be judged differently across health regulators from different countries.

We explain the operationalization of all variables in Section 3.2.

3. Data

In this section, we give an overview of the research context and define the variables and then present descriptive statistics on the international launch window and launch price patterns.

3.1. Research context

We obtained data on launch window and launch price for 58 new drugs in 5 anatomical therapeutic classes (WHO Collaboratory Center for Drug Statistics Methodology) and 50 countries (both developed and developing) worldwide from IMS Health (see Table 2).[3]

We selected these drugs for several reasons. First, these drugs' retail sales account for more than 90% of the total sales volume, meaning that they are consistently used in the outpatient environment. Second, because our analyses required information on launch window and launch price, we were limited to the drugs launched as of February 1994 due to the data storage procedures of our data supplier, IMS Health. Column 1 in Table 2 represents the categories ATC1 and ATC3[4] to which our drugs belong. Column 2 gives the more specific fourth-level ATC code, and the last column gives the numbers of newly launched drugs in our dataset that belong to these categories.

3.2. Variables

We operationalize the launch window (LW_{ij}) of drug i in country j as the difference (in months) between the month in which the drug was first launched anywhere in the world and the month in which the drug was launched in country j (Danzon et al., 2005). The month of launch is the first month in which sales of the new drug are non-zero. As confirmed by IMS Health, our context involves highly regulated markets, and firms at the country level are prepared for launch in terms of product delivery. Therefore, the data are unlikely to be systematically left censored. If a drug i was launched for the first time worldwide in January 2001 in country X and subsequently launched in country Y in June 2001, the launch window of drug i in country X is equal to zero months, and the launch window of drug i in country Y is equal to five months. The launch price (LP_{ij}) of drug i in country j is the natural logarithm of the ex-manufacturer price at launch (the selling price charged by the manufacturer to the wholesaler) in US dollars per gram. To make drug prices comparable across countries, the drug prices in local currencies are converted to US dollars using the currency conversion rate at launch. All of the drugs in our data set were launched for the first time between February 1994 and June 2008. However, not all drugs had been launched in all 50 countries by the end of our observation window. In other words, our data contain right-censored observations.

Despite the fact that the regulatory environment is intrinsically complex, with subtle differences across countries, empirical analysis demands a clear-cut operationalization of the regulatory environment (e.g., Kyle, 2007; Stremersch and Lemmens, 2009; Vernon, Golec, and Keener Hughen, 2006). We measure the regulatory environment, in line with prior research (e.g., Kyle, 2007) and practitioner journals (Kanavos, 2001; PhRMA, 2004), using reports by ethical drug companies (e.g., Novartis, 2004, June 21), OECD (Jacobzone, 2000), and URCH Publishing (Urch, 2001a, 2001b, 2002, 2005) as well as personal conversations with countries' health ministries at the time of launch. Variables describing the regulatory environment are as follows:

- Ex-manufacturer price regulation: the presence (= 1) or absence (= 0) of a direct restriction of price levels by the regulator (Heuer et al., 2007; Kyle, 2007), denoted $REGPRICECONTROL_j$;
- Profit control regulation: the presence (= 1) or absence (= 0) of a threshold on the profits that ethical drug companies can obtain, denoted $REGPROFIT_j$.

[3] Given the sample of 58 new drugs across 50 countries, there are 2900 possible drug-country combinations. However, given appropriate censoring in the data, 2045 of these 2900 possible drug-country pairs remain. Below, we will use these 2045 observations for our descriptive statistics on launch window and price. Because we regress launch price and launch window on other country characteristics, such as regulation, which is unavailable for 8 countries (Egypt, Jordan, Kuwait, Lebanon, Peru, Tunisia, Uruguay, and Venezuela), our model estimation is based on 1,711 drug-country pairs. This number is higher than 1581 (2045–(58 drugs*8 countries)) because some of the right-censored observations overlap with the drug-country observations for which regulatory information is missing.

[4] The numbers in ATC1 and ATC3 refer to the categorization level. The third-level ATC code (ATC3) gives a more specific drug categorization than the first-level ATC code (ATC1).

- Cross-country reference pricing regulation: the presence (= 1) or absence (= 0) of a requirement that the manufacturer submit information on drug prices in other countries (Dukes et al., 2003), denoted $REGCROSS_j$.
- Therapeutic reference pricing regulation: whether health regulators generate a reference price for a cluster of therapeutically similar drugs, above which price the patient is surcharged (= 1), or no such price is generated (= 0) (Danzon and Ketcham, 2003), denoted $REGREF_j$;
- Pharmaco-economic evidence regulation: whether health regulators ask for some proof of the drug's cost effectiveness before launch (=1) or not (=0) (Dickson et al., 2003; Dukes et al., 2003; Garber and Phelps, 1997), denoted $REGPHARMACO_j$;
- Strength of patent protection regulation: an index based on levels of patent laws ranging from 0 to 5 for each country, representing weak to strong patent protection (Ginarte and Park, 1997; Park and Wagh, 2000) and denoted $REGPATENT_j$.

For the market size of a country, ideally we would control for the incidence of the disease in each country. However, given that no such data are available across countries, we control for population size at the time of launch (POP_j), measured by the natural logarithm of the number of inhabitants of country *j*. Countries with a larger population, ceteris paribus, contain more people suffering from a specific disease than do countries with a smaller population size. We also include the natural logarithm of health expenditures per capita in country *j* ($HEALTHEXP_j$) at the time of launch. We obtained information on both variables from the World Bank.

Table 2
Overview of the categories in our sample.

ATC1 and ATC3 codes	ATC4 code	Number of drugs
A Alimentary tract and metabolism		*12*
A2B: drugs for peptic ulcer and reflux disease	A2BC	1
A3A: drugs for functional bowel disorder	A3AE	1
A4A: antiemetics and antinauseants	A4AA	2
A7E: intestinal anti-inflammatory agents	A7EC	1
A8A: antiobesity preparations, excl. diet products	A8AB	2
A10B: blood glucose lowering drugs, excl. insulins	A10BG	3
	A10BX	2
C Cardiovascular system		*11*
C2K: other antihypertensives	C2KX	1
C3D: potassium sparing agents	C3DA	1
C9C: angiotensin II antagonists, plain	C9CA	4
C10A: lipid-modifying agents, plain	C10AA	4
	C10AX	1
G Genito-urinary system and sex hormones		*9*
G3X: other sex hormones and modulators of the genital system	G3XC	1
G4B: other urologicals, incl. antispasmodics	G4BD	2
	G4BE	5
G4C: drugs used in benign prostatic hypertrophy	G4CB	1
J Anti-infectives for systemic use		*19*
J1D: other beta-lactam antibacterials	J1DH	1
J1F: macrolides, lincosamides and streptogramins	J1FA	1
J1M: quinolone antibacterials	J1MA	3
J1X: other antibacterials	J1XX	2
J2A: antimycotics for systemic use	J2AX	2
J5A: direct acting antivirals	J5AE	3
	J5AF	3
	J5AG	1
	J5AH	2
	J5AX	1
R Respiratory system		***7***
R3B: other drugs for obstructive airway diseases, inhalants	R3BB	1
R3D: other systemic drugs for obstructive airway diseases	R3DC	1
R6A: antihistamines for systemic use	R6AX	5

Table 3
Descriptives of variables.

Variable (abbreviation used in Table A.1.)	Average [range]
Launch price in US dollars per gram (V1)[a]	28.051[0.35;3,945,160]
Launch window (V2)	21.86 [0;128]
Ex-manufacturer price regulation (V3)	0.62 [0;1]
Profit control regulation (V4)	0.19 [0;1]
Cross-country reference pricing regulation (V5)	0.69 [0;1]
Therapeutic reference pricing regulation (V6)	0.41 [0;1]
Pharmaco-economic evidence regulation (V7)	0.49 [0;1]
Strength of patent protection (V8)	3.62 [1.98;5]
Population size (V9)	17,192,779 [404,335;294,267,566]
Health expenditures per capita (V10)	1,361 [126;6,015]
Uncertainty avoidance (V11)	68.93 [23;112]
Masculinity (V12)	53.06 [5;95]
Individualism (V13)	57.70 [8;91]
Power distance (V14)	49.66 [11;94]
Competition (V15)	0.61 [0.13;1]
Firm's home country (V16)	0.03 [0;1]
EMEA (V17)	0.54 [0;1]
Summer (V18)	0.14[0;1]
Daily dosage in grams (V19)	0.23 [1.80×10^{-5};6.75]
Inflation (V20)	3.80 [−23;94]

[a] The high maximum launch price in US dollars per gram corresponds to the price of a drug for which the dosage is very small. In the empirical analysis, we use the natural logarithm of launch price. We check for the effect of potential outliers, which we report in Section 5.1.

We obtained data on the dimensions of a country's national culture from Hofstede (1980 and 2001), denoted as follows: uncertainty avoidance (UAI_j), masculinity (MAS_j), individualism (IDV_j), and power distance (PDI_j). To control for the effect of competition on launch window and launch price, we constructed a Herfindahl–Hirschman index ($COMP_{ij}$) for drug *i* in country *j*. This index is constructed by summing the squared market shares (*MS*) (based on revenues in the IMS Health data) of the *m* drugs in the same ATC4 category as drug *i* at the time of launch of drug *i* in country *j* ($COMP_{ij} = \sum_{m=1}^{M} MS_{mj}^2$). A high Herfindahl-Hirschman index indicates that there is little competition for drug *i* in country *j*. We operationalize the home country of the company launching a specific drug *i* in country *j* ($HOME_{ij}$) as a dummy variable (= 1 if the company's headquarters is located in the country of launch *j* and 0 otherwise) (Danzon et al., 2005; Kyle, 2006, 2007).

The variable $SUMMER_{ij}$ is a dummy variable that captures whether the launch of drug *i* in country *j* occurred in July or August for countries in the Northern Hemisphere or in January or February for countries in the Southern Hemisphere. The variable $EMEA_j$ is a dummy variable that has the value 1 if a drug was launched in a country *j* that is part of the European Medicine Evaluation Agency's decision zone (*EMEA*). A drug *i*'s defined daily dosage (DDD_i) in grams is the assumed average maintenance dose per day of a drug used for its main indication in adults (World Health Organization definition). We extracted the inflation rate (annual percentage change in GDP deflator) in country *j* at the time of launch ($INFL_j$) from the World Bank. Finally, we denote the 28 dummy variables for the 29 therapeutic classes to which a drug *i* could belong as ATC_i (see Table 2). We treat the therapeutic class A10BG as the base category. Table 3 gives an overview of the descriptive statistics of the aforementioned variables (for a correlation matrix, see Table A.1. in Appendix A).

3.3. Descriptive statistics

Table 4 provides an overview of the countries' descriptives with regard to launch window and launch price. The first column in Table 4 contains the countries we study, classified by world region. These countries are ranked from early to late launch within their regions based on the launch window in the second column. To calculate mean launch leads and lags, we used the following procedure. We first computed the

mean launch window for each drug across the countries. We then subtracted this mean launch window from each country-specific launch window for that drug. Third, we averaged these country-specific launch windows over all drugs launched in each specific country to obtain mean leads and lags for each specific country. A mean lead (−) indicates that drugs are typically launched early in a country, whereas a mean lag (+) indicates that drugs are typically launched late in a country.

Column 3 in Table 4 shows each country's deviation from the mean launch price across drugs. To calculate these deviations, we first computed the mean launch price for each drug across the countries. Then, within each drug, we computed the percentage deviation of the country-specific price from the mean price over all countries. Finally, we averaged these percentage deviations for each specific country over all drugs launched in that country. A negative deviation means that a drug is typically launched at a relatively low price in a country, whereas a positive deviation indicates that a drug is typically launched at a relatively high price in a country.

Our study is the first to provide an overview of both mean launch lead and lag times and mean launch price deviations across such a broad spectrum of categories and countries, which leads to several new descriptive insights.

First, we find that the US, Germany, and Denmark experience the largest leads in launch. Tunisia, Morocco, and Saudi Arabia experience the largest lags in launch. North America and Western Europe show similar small launch delays. Launch delays are largest in Eastern Europe, Africa, and the Middle East. There is a marked difference in launch timing between Western Europe (fast) and Eastern Europe (slow), although many of these launches occurred recently. Puerto Rico, Japan, and the US have the largest positive deviations from the average launch price worldwide, whereas Egypt, South Africa, and Tunisia show the largest negative deviations from the worldwide average launch price. North America, South America, and Asia show positive deviations from the worldwide average launch price, whereas the other world regions, including Europe, show negative deviations from the average launch price worldwide.

Table 4
Mean lead (−) or lag (+) in launch window and percent deviation from mean price at launch by world region and country.

World region and countries	Mean lead (−) or lag (+) in launch window (in months)	% deviation from mean price at launch per gram
North America	**−8.95**	**37.87**
US	−17.17	37.79
Canada	−7.50	−1.57
Puerto Rico	−7.21	93.09
Mexico	−3.94	22.16
Western Europe	**−5.81**	**−8.15**
Germany	−15.59	−9.17
Denmark	−10.65	−5.35
UK	−9.82	−0.14
Austria	−9.13	−9.92
Switzerland	−8.97	0.21
Ireland	−8.08	−5.22
Sweden	−7.11	−8.48
Netherlands	−6.95	−6.93
Finland	−6.44	−4.39
Norway	−5.87	3.83
Spain	−4.03	−17.22
Belgium	−3.45	−13.61
Luxemburg	−2.22	−12.78
Portugal	−1.66	−11.47
Italy	−1.01	−13.26
France	−0.46	−12.44
Greece	2.06	−12.21
South America	**−0.43**	**7.93**
Brazil	−6.79	14.43
Argentina	−6.36	0.89
Colombia	−3.12	33.67
Chile	−2.27	−8.19
Venezuela	1.97	17.49
Uruguay	3.95	12.72
Peru	4.29	−4.20
Ecuador	4.91	−3.39
Oceania	**0.10**	**−8.02**
Australia	−1.55	−11.82
New Zealand	1.75	−4.21
Asia	**5.16**	**11.01**
Philippines	−2.17	−12.15
Japan	6.89	47.89
Korea	10.75	−2.71
Eastern Europe	**8.74**	**−1.62**
Czech Republic	5.03	1.58
Estonia	5.21	−3.51
Hungary	5.68	−5.54
Poland	8.91	1.71
Latvia	9.55	−5.78
Slovakia	12.77	0.78
Lithuania	14.02	−0.61
Africa and the Middle East	**14.51**	**−13.31**
Kuwait	4.42	−1.81
South Africa	5.14	−26.11
United Arabic Emirates	6.49	−4.33
Lebanon	6.77	−16.32
Jordan	12.37	−7.89
Egypt	17.86	−29.10
Saudi Arabia	19.40	−13.37
Morocco	20.88	−8.67
Tunisia	37.28	−20.82

4. Model

Let LW_{ij}^* be the launch window of drug i in country j, and let LP_{ij}^* be the natural-logarithm-transformed ex-manufacturer price at launch per gram of drug i in country j. We do not always observe the actual values of LW_{ij}^* and LP_{ij}^* because right censoring is present. Observed values are denoted by LW_{ij} and LP_{ij}. Censoring occurs for the drug-country combinations for which we do not observe a launch at the end of our observation window. We denote as C_{ij} the censoring time, or the time between the end of the observation period and the drug- and country-specific launch date. For the observed launch window, we have that:

$$\begin{cases} LW_{ij} = LW_{ij}^* \quad if\ LW_{ij}^* \le C_{ij}\,, & (a) \\ LW_{ij} = C_{ij}\ otherwise. & (b) \end{cases} \tag{1}$$

Furthermore, the launch price LP_{ij} is only observed in the selected sample, for which $LW_{ij}^* \le C_{ij}$, and thus $LP_{ij} = LP_{ij}^*$.

We have the following set of simultaneous equations:

$$\begin{cases} LW_{ij}^* = \alpha_1 LP_{ij}^* + \alpha_2 \left(LP_{ij}^*\right)^2 + \delta' \mathbf{Z}_{ij1} + u_{ij1} & (a) \\ LP_{ij}^* = \beta_1 LW_{ij}^* + \beta_2 \left(LW_{ij}^*\right)^2 + \gamma' \mathbf{Z}_{ij2} + u_{ij2} & (b) \end{cases} \tag{2}$$

The vector $\mathbf{Z}_{ij1}$ contains the exogenous variables for the launch window equation, and $\mathbf{Z}_{ij2}$ contains the exogenous variables for the launch price equation. The error terms u_{ij1} and u_{ij2} are allowed to be correlated. Following Garen (1984), we consider LW_{ij}^* and LP_{ij}^* as endogenous variables. Indeed, the firm and the regulator may both select the launch window with the goal of influencing the launch price and select the level of launch price with the goal of influencing the launch window. The omitted variables in u_{ij1} include non-observable strategic variables used by the firm and the regulator to select the optimal value of LW_{ij}^*. One may expect that these strategic variables would be

correlated with the launch price. The omitted variables in u_{ij2} then include unobservable strategic variables used by the firm and the regulator to select the optimal value of LP_{ij}^*. Similarly, one may expect that these strategic variables would be correlated with the launch window. The inclusion of the quadratic terms in Eq. (2a,b) allows the testing of H1 and H2. We will test the robustness of our findings through other parametric and non-parametric specifications.

To account for the endogeneity, we estimate the system of Eq. (2a, b) using a three-stage least squares (3SLS) procedure, as in Bayus, Kang, & Agarwal (2007). Additionally, we correct for right-censoring and selectivity using the procedure described in Vella (1993) or Wooldridge (2002).

To estimate the structural launch window Eq. (2a), we first estimate the reduced form of the launch price equation by a Tobit regression of the second type (to account for the fact that we only observe prices if the drug has already been launched). This launch price equation contains two variables that influence launch price but not launch window, namely DDD_i and $INFL_j$, which serve as instruments for the launch price in the launch window equation. The Sargent test does not lead to a rejection of the validity of these instruments ($p=0.46$). We add the generalized residuals of the reduced launch price equation to Eq. (2a) as a correction term. We validate the strength of the instruments by comparing Tobit regression models of launch window on the exogenous variables with and without the instruments DDD_i and $INFL_j$. The corresponding likelihood ratio test demonstrated these instruments to be significant ($LR=625.11$, $p<0.01$). The inclusion of instruments led to a relative increase in pseudo R-squared of 10%.

To estimate the structural launch price Eq. (2b), we first estimate the reduced form of the launch window equation by a Tobit regression of the first type (to account for the right censoring). This launch window equation contains two variables that influence launch window but not launch price, namely, $SUMMER_{ij}$ and $EMEA_j$, which serve as instruments for the launch window in the launch price equation. The Sargent test does not indicate a rejection of the validity of these instruments ($p=0.75$). We add the generalized residuals of the reduced launch window equation as a correction term to Eq. (2b). We tested for the strength of the instruments by computing the (pseudo) R-squared of the regression models of launch delay on the exogenous variables with and without the instruments $SUMMER_{ij}$ and $EMEA_j$. The corresponding likelihood ratio test demonstrated these instruments to be significant ($LR=153.80$, $p<0.01$). The inclusion of instruments led to a relative increase in pseudo R-squared of 5%.

Replacing the vectors $\mathbf{Z}_{ij1}$ (in Eq. (2a)) and $\mathbf{Z}_{ij2}$ (in Eq. (2b)) by the exogenous variables leads to Eq. (3) and Eq. (4), respectively:

$$\begin{aligned} LW_{ij} = {} & \delta_0 + a_1 LP_{ij} + a_2 LP_{ij}^2 + \phi_1 \nu_{LP} + \\ & \delta_1 REGPRICECONTROL_j + \delta_2 REGPROFIT_j + \delta_3 REGCROSS_j + \delta_4 REGREF_j + \\ & \delta_5 REGPHARMACO_j + \delta_6 REGPATENT_j + \delta_7 POP_j + \delta_8 HEALTHEXP_j + \delta_9 UAI_j + \\ & \delta_{10} MAS_j + \delta_{11} IDV_j + \delta_{12} PDI_j + \delta_{13} COMP_{ij} + \delta_{14} HOME_{ij} + \delta_{15} SUMMER_{ij} + \\ & \delta_{16} EMEA_j + \sum_{i=1}^{28} \xi_i ATC_i + \eta_{ij1} \end{aligned} \quad (3)$$

$$\begin{aligned} LP_{ij} = {} & \gamma_0 + b_1 LW_{ij} + b_2 LW_{ij}^2 + \theta_1 \nu_{LW} + \\ & \gamma_1 REGPRICECONTROL_j + \gamma_2 REGPROFIT_j + \gamma_3 REGCROSS_j + \gamma_4 REGREF_j + \\ & \gamma_5 REGPHARMACO_j + \gamma_6 REGPATENT_j + \gamma_7 POP_j + \gamma_8 HEALTHEXP_j + \\ & \gamma_9 UAI_j + \gamma_{10} MAS_j + \gamma_{11} IDV_j + \gamma_{12} PDI_j + \gamma_{13} COMP_{ij} + \gamma_{14} HOME_{ij} + \\ & \gamma_{15} DDD_i + \gamma_{16} INFL_j + \sum_{i=1}^{28} \zeta_i ATC_i + \eta_{ij2} \end{aligned} \quad (4)$$

where ν_{LP} and ν_{LW} represent the generalized residuals or the *selectivity variables*. The use of generalized residuals is equivalent to the control function approach; the terms $\phi_1 \nu_{LP}$ and $\theta_1 \nu_{LW}$ in Eqs. (3) and (4) are the control functions (see Petrin and Train, 2010, for another application of control functions). The system of Eqs. (3) and (4) is then jointly estimated as a system of equations using generalized least squares. We also included random country effects in the equations to account for the fact that there are repeated observations across countries for most

Table 5
Estimation results of system equation with random country effects.

	Hypothesis number (hypothesized effect)	Launch window equation (LWE)			Hypothesis number (hypothesized effect)	Launch price equation (LPE)		
		Coefficient	S.E.	Sign.		Coefficient	S.E.	Sign.
Constant (δ_0,γ_0)		−41.90	5.99	***		3.19	0.86	***
Launch price (a_1)		−5.65	0.80	***		/	/	
Launch price*launch price (a_2)	H1 (U)	0.33	0.04	***		/	/	
Launch window (b_1)		/	/			0.03	5.10×10^{-3}	***
Launch window*launch window (b_2)		/	/		H2 (∩)	-1.79×10^{-4}	5.89×10^{-5}	***
Selectivity variable (ϕ_1,θ_1)		2.77	0.69	***		−2.32	2.81	
Ex-manufacturer price regulation (δ_1,γ_1)	H3a (+)	3.75	2.55		H3b (−)	−0.14	0.09	
Profit control regulation (δ_2,γ_2)	H4a (+)	16.07	3.02	***	H4b (−)	−0.14	0.11	
Cross-country reference pricing regulation (δ_3,γ_3)	H5a (−)	−3.44	2.45		H5b (+)	0.06	0.12	
Therapeutic reference pricing regulation (δ_4,γ_4)	H6a (+)	4.19	1.92	**	H6b (−)	−0.13	0.09	
Pharmaco-economic evidence regulation (δ_5,γ_5)	H7a (+)	3.40	1.76	*	H7b (−)	−0.03	0.09	
Strength of patent protection (δ_6,γ_6)	H8a (−)	−5.96	1.89	***	H8b (−)	−0.07	0.09	
Population size (δ_7,γ_7)		−1.98	0.79	**		0.07	0.04	*
Health expenditures per capita (δ_8,γ_8)		19.23	1.75	***		-7.37×10^{-3}	0.09	
Uncertainty avoidance (δ_9,γ_9)		−0.20	0.06	***		-1.45×10^{-3}	2.82×10^{-3}	
Masculinity (δ_{10},γ_{10})		0.25	0.05	***		-1.71×10^{-3}	2.33×10^{-3}	
Individualism (δ_{11},γ_{11})		−0.37	0.07	***		-3.62×10^{-4}	3.22×10^{-3}	
Power distance (δ_{12},γ_{12})		0.33	0.08	***		-6.04×10^{-3}	3.82×10^{-3}	
Competition (δ_{13},γ_{13}) (reverse-scored)		2.57	2.38			0.65	0.24	***
Firm's home country (δ_{14},γ_{14})		−6.34	2.41	***		0.44	0.23	*
Summer (δ_{15})		−1.96	1.14	*		/	/	
EMEA (δ_{16})		−4.01	2.14	*		/	/	
Daily dosage (γ_{15})		/	/			−3.08	0.18	***
Inflation (γ_{16})		/	/			9.79×10^{-3}	8.29×10^{-3}	
Anatomical therapeutic classes (ξ_i,ζ_i; $i=1\ldots28$)				***				***
N		1711				1711		
Adjusted R-Squared		0.26				0.66		

Significance (sign.) levels (two-sided): *: $p<0.10$; **: $p<0.05$; ***: $p<0.01$. S.E.: standard error

drugs. These random effects thus introduce a correlation, called the within-group correlation, between the error terms corresponding to the same country.

In sum, the coefficients a_1 and a_2 allow us to test hypothesis 1 (the causal effect of launch price on launch window, controlling for the joint determination of launch window and launch price), whereas the coefficients b_1 and b_2 allow us to test hypothesis 2 (the causal effect of launch window on launch price, controlling for the joint determination of launch window and launch price). The variables ν_{LW} and ν_{LP} capture the simultaneous determination of launch window and launch price. These variables measure whether launch window is strategically selected as a function of launch price and vice versa.

For clarification, note that the expressed non-linear relationships in Eqs. (3) and (4) are not each other's inverse. Even in a simple regression context, with a fitted regression equation $\hat{Y} = a + bX$, it is not true that a regression of X on Y yields an estimated regression equation $\hat{X} = (Y - a)/b$. Thus, the estimated slope of regressing Y on X is not the inverse of the estimated slope of regressing X on Y. If there is only one explanatory variable, the sign of the slopes will be equal, but one loses this property when controlling for other variables. In the special case of curvilinear effects, as in our case, the effects are still not each other's inverse.

5. Results

We present the explanatory variables in the first column of Table 5. The second column contains the hypothesis number and the sign of the expected effect for the launch window equation. We report the parameter estimates, their standard errors, and the significance levels for the launch window equation in the third, fourth, and fifth columns. The sixth column in Table 5 shows the hypothesis number and the sign of the hypothesized effect for the launch price equation. The seventh, eight, and ninth columns in Table 5 present the parameter estimates, their standard errors, and the significance levels for the launch price equation. We find evidence for random country effects in the launch window equation in the form of an intra-country correlation coefficient of 8%, whereas we do not find this evidence for the launch price equation. We first discuss the results of the launch window equation, and we then turn to the results of the launch price equation.

Consistent with hypothesis one (H1), we find a U-shaped effect of launch price on launch window ($a_1 = -5.65$, $p<0.01$, and $a_2 = 0.33$, $p<0.01$). This relation is depicted graphically in Fig. 1, based on the full model coefficients within our observation window.[5] The values of the exogenous variables are set at their averages across the sample. Fig. 1 shows that, on average, the launch window is shortest at Ln (launch price) =8.63 (standard error of 1.08). This means that the launch window is shortest at a launch price that deviates from the lowest price point by 53%.

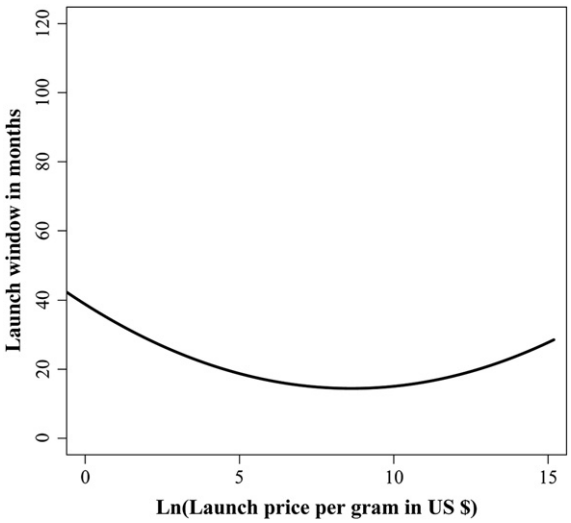

Fig. 1. Effect of launch price on launch window.

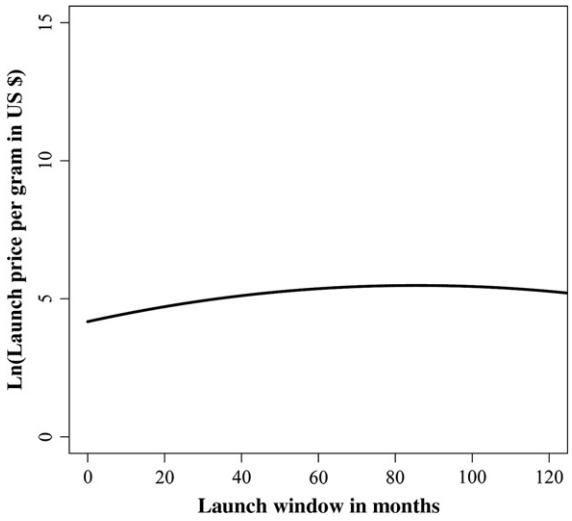

Fig. 2. Effect of launch window on launch price.

The effect of ex-manufacturer price regulation is non-significant ($p = 0.15$), although it does have the expected positive sign (H3a). As expected, profit regulation ($\delta_2 = 16.07$, $p<0.01$) has a positive influence on launch window (H4a).

The effect of cross-country reference pricing regulation is not significant (H5a). Countries with therapeutic reference pricing regulation ($\delta_4 = 4.19$, $p<0.05$) and pharmaco-economic evidence regulation ($\delta_5 = 3.40$, $p<0.10$) experience a longer launch window (H6a and H7a), whereas countries with stronger patent protection have a shorter launch window ($\delta_6 = -5.96$, $p<0.01$) (H8a). Next, we discuss the results for the control variables in the launch window equation. Launch occurs earlier in countries with a larger population ($\delta_7 = -1.98$, $p<0.05$), whereas health expenditures per capita significantly lengthens the launch window ($\delta_8 = 19.23$, $p<0.01$).

For culture, countries that are high in uncertainty avoidance ($\delta_9 = -0.20$, $p<0.01$) or in individualism ($\delta_{11} = -0.37$, $p<0.01$) have a shorter launch window than countries that are low in uncertainty avoidance or low in individualism, respectively. Countries that are high in masculinity ($\delta_{10} = 0.25$, $p<0.01$) and power distance ($\delta_{12} = 0.33$, $p<0.01$) have a longer launch window than do countries that are low in masculinity and power distance. The extent of competition in the new drug's category does not significantly influence the launch window. As expected, firms launch new drugs faster in their home country ($\delta_{14} = -6.34$, $p<0.01$). Firms also launch faster in the summer ($\delta_{15} = -1.96$, $p<0.10$) and in countries belonging to the EMEA zone ($\delta_{16} = -4.01$, $p<0.10$). The therapeutic category dummies are jointly significant ($p<0.01$); we do not report their specific estimates for reasons of brevity (but they are available from the authors upon request).

Turning to the launch price equation, we find support for the inverted U-shaped effect of launch window on launch price posited in H2 ($b_1 = 0.03$, $p<0.01$ and $b_2 = -1.79\times10^{-4}$, $p<0.01$). This relation is depicted graphically in Fig. 2 (based on the full model coefficients; the values of launch window on the horizontal axis of Fig. 2 remain within our observation window). Fig. 2 shows that a launch

[5] The horizontal axis becomes negative because the launch price per gram in US dollars is ln-transformed.

window of 85 months (standard error of 17 months) is associated with the highest launch price. Because of the lag between the initial research on a compound that could become a drug and the time when the drug actually enters the market, Grabowski & Kyle (2007) estimate a drug's average market exclusivity period to be approximately 11 years, but with a high variance surrounding this value. The launch window of 7 years thus seems to have face validity. After 7 years, ethical drug companies and health regulators increasingly align on lower prices for the reasons we stipulated in the theory section above. Interestingly, the launch price decreases moderately between 7 and 11 years after launch. This is due to the selection of drugs that launched during our 12-year data window, the longest time span available under IMS Health data storage procedures. We expect that the decrease beyond 7 years would be more prominent if we had been able to trace drug launches over a longer data window (e.g., 20 years).

Surprisingly, although the effect signs are in line with our expectations, regulatory restrictions do not significantly influence launch price, contrary to H3b-H8b. Stremersch & Lemmens 2009 and Ekelund & Persson (2003) found that launch prices in regulated markets may not be higher than launch prices in non-regulated markets, whereas prices in the regulated markets decrease at a much higher rate than prices in non-regulated markets. Danzon & Chao (2000b) have also shown the latter. Apparently, regulatory restrictions are more useful to regulators to constrain the prices of mature drugs than those of newly launched drugs. From conversations with the industry, we speculate that regulators may have limited information on newly launched drugs to guide potential price or profit caps. Pharmacoeconomic evidence in a given country is more limited at launch than it is later on in a drug's life cycle. Therapeutic benefits, as compared to alternatives, are still partially unclear because real-life medical practice may lead to different therapeutic outcomes as compared to controlled clinical trials. Profits that the firm may obtain from a new drug are relatively unclear compared to the profits it may obtain from a mature drug because the extent to which a new drug diffuses in medical practice may be uncertain.

Launch occurs at a higher price in large countries (i.e., a large population) than in small countries ($\gamma_7 = 0.07$, $p<0.10$). We do not find any evidence for an effect of health expenditures per capita on launch price. As mentioned before, increasing health expenditures per capita may indicate both a higher willingness to provide good healthcare to citizens and a higher budget pressure, which may cancel each other out. A country's culture does not influence the launch price of a new drug.

Competition drives down launch price ($\gamma_{13} = 0.65$, $p<0.01$; reverse-scored). Firms obtain higher launch prices in their domestic market than they do in foreign markets ($\gamma_{14} = 0.44$, $p<0.10$). As expected, the higher the required daily dosage of a drug, the lower the price per gram of the drug ($\gamma_{15} = -3.08$, $p<0.01$). The therapeutic category dummies are also jointly significant ($p<0.01$) in the launch price equation.

As to the selectivity variables, we find that the coefficient of this variable in the launch window equation ($\phi_1 = 2.77$, $p<0.01$) is significant. If launch price is higher than expected based on the values of the explanatory variables, the launch window is also longer. This finding may indicate that health regulators act strategically in delaying market access for expensive drugs, which is against the interests of the ethical drug company. The parameter θ_1 in the launch price equation is non-significant.

5.1. Robustness checks

We conducted many robustness checks, which are presented in Table 6. Adjusted R-squared measures are only given for models that are computed from the full sample.

Table 6
Robustness checks.

Model specification	Effect of launch price on launch window U-shaped?	Effect of launch window on launch price inverted U-shaped?
Linear model	/	/
Cubic model	Yes	Yes
Semi-parametric model	Yes	Yes
Exclusion of ATC1 category 1	Yes	Yes
Exclusion of ATC1 category 2	Yes	Yes
Exclusion of ATC1 category 3	Yes	No
Exclusion of ATC1 category 4	Yes	Yes
Exclusion of ATC1 category 5	Yes	Yes
Exclusion of country with highest	Yes	Yes
Nr of competitors instead of HI	Yes	Yes
Size of population older than 15 years instead of total population size	Yes	Yes

First, we checked whether the functional form that we chose (quadratic) is appropriate. We find that our model outperforms a linear model (adjusted R-squared of 0.23 and 0.65 for the linear model versus 0.26 and 0.66 for the quadratic model). Our model has the same fit as a cubic model (adjusted R-squared of 0.26 and 0.66 for both models). The pattern of the effect in the cubic model approaches the pattern of the effect in the quadratic model. Thus, we opt for the parsimony of the quadratic model. We also estimated Eq. (2a,b) in a semi-parametric way. The model specification for the launch window Eq. (2a) becomes:

$$LW_{ij}^{*} = m\left(LP_{ij}^{*}\right) + \delta' \mathbf{Z}_{ij1} + u_{ij1} \tag{6}$$

with m a smooth but unknown function. This is a semi-parametric model because the exogenous variables still enter the model in a linear way. The relationship between launch price and launch window is, however, completely non-parametric. We then estimate the regression function m by generalized additive models. We use the same approach for the semi-parametric estimation of the price equation (Eq. (2b)). The pattern of the effect in the semi-parametric model approaches the pattern of the effect in the quadratic model.

Second, we randomly excluded specific therapeutic categories, countries and drugs. Our model results were robust to such exclusions, as shown in Table 6 for the exclusion of complete categories (results of country and drug exclusions available from the authors upon request). The only exception is the exclusion of ATC1 category 3, in which the inverted U-shaped effect of launch window on launch price turns non-significant. We also checked for potential outliers by excluding the country with the highest price for each molecule. Our results remain robust.

Third, we examined alternate operationalizations of several variables. For instance, Table 6 shows that the model is robust to alternate measures of competition (i.e., using number of competitors instead of the Herfindahl index we mentioned earlier) and population size (i.e., only counting people older than 15 years of age). Alternate operationalizations of control variables yielded similar effects.

6. Discussion and implications

This paper yields interesting insights into the complex phenomenon of international launch behavior by ethical drug firms and their interactions with health regulators. While controlling for the simultaneity of the decisions on international launch timing and launch price, we find

that international launch price has a U-shaped effect on launch window, whereas the international launch window has an inverted U-shaped effect on launch price. Health regulators behave strategically in delaying the launch of more expensive new drugs. Moreover, we gain further insight into factors influencing the launch window and launch price, respectively. Whereas regulation influences the launch window, it does not affect the launch price. Our findings give insights to managers and public policy makers, and the limitations of our work yield opportunities for future research.

International launch window and price have an important impact on a company's bottom line (Danzon et al., 2005; Wagner and McCarthy, 2004). Stremersch & Lemmens 2009 showed that the launch window of pharmaceuticals does not influence the sales pattern. However, because we show that the launch window and launch price are interrelated, the launch window will influence the revenues of firms through the launch price and the time that the drug is on the market under patent protection. The contribution of our results to ethical drug firms primarily lies in enhancing their understanding of international launch window and price patterns. The patterns that we find inform firms on launch windows and prices that are common across countries in our sample. This descriptive information and the interconnection between launch price and launch window allow them to make more informed decisions about international market entry.

Our research can also inform public policy administrators on launch windows and launch prices, both of which are relevant to healthcare policy. The popular press sometimes points at individual cases of how a drug was launched late in a country or how the price of a specific drug is higher in one country as compared to other countries. For example, the anti-allergy drug Xyzall was launched in the US with a significant delay in comparison to many other countries (Global Insight, 2007, May 30). The launch price of Pfizer's statin Lipitor was €0.60 in Paris (France), whereas the launch price of that same pill was $3.98 in Philadelphia (USA) (Capell, 2003, February 17). Typically, such stories in the popular press are based on only a single case. For every country, we can come up with at least one drug that was introduced very late or priced very highly. The popular press typically generalizes beyond the single case that they cite to make inferences about the country's healthcare policy, and often to support criticism of it. This study provides public policy analysts with more quantitative evidence on a broad sample of countries and categories.

Furthermore, our model can provide insights into hypothetical situations as long as such situations occur within the bounds of variation observed in our data. Thus, we can gauge the effect of a change in launch window on launch price and vice versa using the estimates of the causal effects between the two decision variables we reported above, controlling for the simultaneity in the launch price and launch window decisions. For example, Lipitor's (atorvastatin) launch in Belgium in 1998 had a launch window of 15 months. If the launch of Lipitor had occurred one month earlier, its launch price in Belgium would have been 2.51% (S.E. = 0.43%) lower than its actual launch price. Thus, health regulators may not only increase patients' access to new drugs by granting earlier access, but such early access may also come at a lower price. Ethical drug companies accept such lower prices because they have more time to recoup their R&D investment. A similar exercise for Lipitor in all countries reveals that, in relative terms, the largest launch price decrease would be in the UK (−3.04%) and the smallest launch price decrease would be in Tunisia (−1.21%). However, a 10% increase in the price of Lipitor in Belgium (from $70.64 to $77.70) would have led to a decrease in the launch window of 0.25 months, which translates to 8 days (S.E. = 3 days). A similar exercise for Lipitor in all countries reveals a decrease in launch windows between 0.22 months, which translates to 7 days (New Zealand), and 0.29 months, which translates to 9 days (Columbia). Although such calculations are conditional upon other variables remaining equal and are purely illustrative, they provide insight into the magnitude of the interdependencies of these two important decisions, launch timing and launch price.

7. Limitations and future research

First, our results are context specific because the focus is on the pharmaceutical industry. Therefore, one should use caution in generalizing beyond this research context. Although one could argue that this gives the research a narrow appeal, one should consider the economic and substantive importance of this industry (Stremersch, 2008; Stremersch and Van Dyck, 2009).

Second, we do not specify the objective functions of firms and health regulators. The reason is that it is not clear whether the objective function of health regulators is access to healthcare or controlling healthcare budgets. Although a model of the dynamic game between a health regulator and an ethical drug company would be of great interest, it is considered to be outside of the scope of this paper.

Third, one can easily critique the simple operationalization of the complex regulatory environment. Operationalizing the regulatory context across countries in more detail, while challenging, could be insightful. For example, further research could try to explicitly take into account the interdependencies that occur between countries because of the cross-country reference pricing regulation. We controlled for this system through a dummy variable, but richer insights could be obtained by gathering data on the reference set of each country that applies such a system.

Fourth, launch window and launch price decisions are made in a complex environment. Although we control for many variables for the sake of completeness, we acknowledge that we may not capture all possible variables. However, given the diversity of the variables that we control for and the many robustness checks we performed, we feel confident about our findings.

Fifth, although we provide evidence of variation in drugs' availability and launch prices across countries, we do not have data on the prices that patients actually pay (the level of "co-pay"). Even if a drug's price is low, patients in some countries can still be excluded from access to this drug because of a high co-payment. Data on how much patients actually co-pay across countries would add insight, but to our knowledge, these data are unavailable at the drug and country level.

Sixth, beyond launch timing and launch price, one may consider the launch sequence of a new drug across countries. Although optimizing the launch sequence for new drugs is outside the scope of the present paper, it is certainly of high relevance given cross-country spill-over (e.g., due to cross-country reference pricing) in drug prices.

Seventh, we find that the effect of regulation on drug launch prices is non-significant. Although this confirms earlier findings of Stremersch & Lemmens (2009) and Ekelund & Persson (2003), we can only speculate as to the reasons why this happens (i.e., higher budget pressure for the regulator from mature drugs than from newly launched drugs). This reasoning is in line with Danzon & Chao (2000b), who show that regulation has an effect on the price evolution of the life cycle of a drug. Future research that examines the health regulator's use of regulatory restrictions on drug prices over a drug's life cycle may be very valuable as it may uncover explanations for the patterns we discovered. However, given our focus on launch, this investigation is beyond the scope of the present paper.

Eighth, the drug prices in our model are expressed in a common denominator, namely, US dollars per gram, as converted from the local currency by IMS Health in the month of launch. A formal analysis of the macro-economic influence of the exchange rate on drug prices is, although potentially interesting, beyond the scope of the present paper. Our findings are robust to the exclusion of specific countries as well as exclusion of specific time periods from the sample, alleviating concerns that our findings may be driven by countries with strong currency fluctuation in specific time periods (e.g., Brazil in 2002–2003).

Given the business and societal relevance of international launch and pricing of pharmaceuticals and the limitations of prior studies in this field, including our present study, we expect much more work on this topic to be undertaken by scholars in both economics and marketing.

Appendix A

Correlation matrix.

	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19	V20
V1	1.00																			
V2	**−0.09**	1.00																		
V3	0.01	**0.12**	1.00																	
V4	0.01	**0.12**	−0.03	1.00																
V5	0.01	**0.09**	**0.47**	**0.05**	1.00															
V6	−0.03	−0.03	−0.04	**−0.22**	**0.10**	1.00														
V7	−0.00	−0.02	0.04	0.01	**0.23**	**0.20**	1.00													
V8	−0.03	**−0.22**	**−0.11**	**−0.13**	−0.02	**0.09**	0.02	1.00												
V9	−0.00	**−0.09**	**−0.12**	**0.10**	**−0.40**	**−0.10**	**−0.16**	**0.24**	1.00											
V10	0.02	**−0.18**	**0.06**	**−0.30**	**0.16**	**0.13**	**0.08**	**0.62**	**−0.08**	1.00										
V11	0.01	**0.22**	**0.24**	**0.14**	**0.24**	**−0.09**	**−0.20**	**−0.48**	−0.02	**−0.33**	1.00									
V12	−0.01	**0.05**	**−0.06**	−0.02	0.02	**−0.07**	**−0.25**	0.04	**0.24**	**0.10**	**0.25**	1.00								
V13	−0.01	**−0.15**	**−0.10**	**−0.15**	**0.21**	**0.35**	**0.27**	**0.52**	**−0.15**	**0.62**	**−0.51**	0.00	1.00							
V14	0.00	**0.20**	**0.05**	**0.11**	**−0.17**	**−0.11**	**−0.10**	**−0.63**	**0.26**	**−0.57**	**0.57**	**0.19**	**−0.62**	1.00						
V15	**0.15**	−0.02	−0.00	0.04	0.04	0.00	**0.06**	−0.04	**−0.09**	**−0.06**	−0.02	−0.03	0.03	−0.03	1.00					
V16	−0.00	**−0.14**	**−0.14**	−0.04	**−0.17**	**−0.09**	**−0.07**	**0.25**	**0.21**	**0.27**	**0.14**	**0.06**	**0.19**	**−0.09**	−0.04	1.00				
V17	0.01	−0.01	0.02	**0.08**	**0.32**	**0.19**	**0.08**	0.03	**−0.43**	**0.15**	**0.11**	**−0.09**	**0.33**	**−0.25**	0.03	**−0.07**	1.00			
V18	0.02	**−0.04**	−0.03	**−0.08**	**−0.14**	−0.03	−0.04	0.01	**0.05**	**−0.05**	−0.04	−0.04	**−0.08**	0.04	−0.02	0.00	**−0.07**	1.00		
V19	**−0.36**	**0.13**	**−0.05**	−0.00	0.04	0.00	0.00	**0.08**	0.03	**0.05**	**−0.07**	−0.03	0.03	**−0.06**	**−0.06**	0.04	−0.03	0.00	1.00	
V20	0.04	**0.05**	−0.02	**0.10**	**−0.07**	**−0.12**	**−0.12**	**−0.30**	**0.07**	**−0.35**	**0.12**	**0.09**	**−0.26**	**0.30**	-.02	**−0.09**	**−0.14**	0.02	−0.00	1.00

Correlations in bold are significant at $p<0.05$ (two-sided tests).
Table 3 in Section 3.3 defines the labels of the variables used in this matrix. This correlation matrix shows correlations between the variables as they are operationalized and included in the model.

References

Abbott, T. A. (1995). Price regulation in the pharmaceutical industry: Prescription or placebo? *Journal of Health Economics*, *14*, 551–565.

Bayus, B. L., Kang, W., & Agarwal, R. (2007). Creating growth in new markets: A simultaneous model of firm entry and price. *The Journal of Product Innovation Management*, *24*, 139–155.

Berndt, E. R. (2000). International comparisons of pharmaceutical prices: What do we know, and what does it mean? *Journal of Health Economics*, *19*(2), 283–287.

Bolton, R. N., & Myers, M. B. (2003). Price-based global market segmentation for services. *The Journal of Marketing*, *67*, 108–128 (July).

Borrell, J. R. (1999). Pharmaceutical price regulation: A study on the impact of the rate-of-return regulation in the UK. *PharmacoEconomics*, *15*(3), 291–303.

Boulding, W., & Christen, M. (2003). Sustainable pioneering advantage? Profit implications of market entry order. *Marketing Science*, *22*(3), 371–392.

Burgess, S. M., & Steenkamp, J. B. E. M. (2006). Marketing renaissance: How research in emerging markets advances marketing science and practice. *International Journal of Research in Marketing*, *23*(4), 337–356.

Capell, K. (2003, February 17). Commentary: Europe pays a high price for cheap drugs. *Business Week*. URL. http://www.businessweek.com/magazine/content/03_07/b3820139_mz034.htm Last accessed on April 27th 2011.

Chandy, R. K., & Tellis, G. J. (1998). Organizing for radical product innovation: The overlooked role of willingness to cannibalize. *Journal of Marketing Research*, *35*(4), 474–487.

Chintagunta, P. K., & Desiraju, R. (2005). Strategic pricing and detailing behavior in international markets. *Marketing Science*, *24*(1), 67–80.

Cohen, J., Faden, L., Predaris, S., & Young, B. (2007). Patient access to pharmaceuticals: An international comparison. *The European Journal of Health Economics*, *8*(3), 253–266.

Comanor, W. S., & Schweitzer, S. O. (2007). Determinants of drug prices and expenditures. *Managerial and Decision Economics*, *28*(4–5), 357–370.

Danzon, P. M. (1998). The economics of parallel trade. *PharmacoEconomics*, *13*(3), 293–304.

Danzon, P. M., & Chao, L. W. (2000). Cross-national price differences for pharmaceuticals: How large, and why? *Journal of Health Economics*, *19*(2), 159–195.

Danzon, P. M., & Chao, L. W. (2000). Does regulation drive out competition in pharmaceutical markets? *Journal of Law and Economics*, *43*(2), 311–357.

Danzon, P. M., & Furukawa, M. F. (2003). Prices and availability of pharmaceuticals: Evidence from nine countries. *Health Affairs*, *22*(6), 521–536.

Danzon, P. M., & Furukawa, M. F. (2006). Prices and availability of biopharmaceuticals: An international comparison. *Health Affairs*, *25*(5), 1353–1362.

Danzon, P. M., & Ketcham, J. (2003). *Reference pricing of pharmaceuticals for Medicare.* Evidence from Germany, the Netherlands and New Zealand. NBER, Cambridge, MA: NBER Working paper 10007.

Danzon, P. M., & Kim, J. D. (1998). International price comparisons for pharmaceuticals: Measurement and policy issues. *PharmacoEconomics*, *14*(1), 115–128.

Danzon, P. M., Wang, R. Y., & Wang, L. (2005). The impact of price regulation on the launch delay of new drugs: Evidence from twenty-five major markets in the 1990s. *Health Economics*, *14*(3), 269–292.

Dawar, N., & Parker, P. (1994). Marketing universals: Consumers' use of brand name, price, physical appearance, and retailer reputation as signals of product quality. *The Journal of Marketing*, *58*(April), 81–95.

Dekimpe, M. G., Parker, P. M., & Sarvary, M. (2000). Globalization: Modeling technology adoption timing across countries. *Technological Forecasting and Social Change*, *63*(1), 25–42.

Dickson, M., Hurst, J., & Jacobzone, S. (2003). *Survey of pharmaco-economic assessment activity in eleven countries.* OECD, Paris, France: OECD Health Working paper.

DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: New estimates of drug development costs. *Journal of Health Economics*, *22*(2), 151–185.

Dukes, M. N. G., Haaijer-Ruskamp, F. M., de Jonckheere, C. P., & Rietveld, A. H. (2003). *Drugs and money.* Prices, affordability and cost containment*the Netherlands*.. Amsterdam: IOS Press.

Ekelund, M., & Persson, B. (2003). Pharmaceutical pricing in a regulated market. *The Review of Economics and Statistics*, *85*(2), 298–306.

Eliashberg, J., & Helsen, K. (1996). *Modeling lead/lag phenomena in global marketing.* The case of VCRs. *Working paper*. Philadelphia, PA: The Wharton School, University of Pennsylvania.

Garattini, L., & Ghislandi, S. (2007). Should we really worry about "launch delays" of new drugs in OECD countries? *The European Journal of Health Economics*, *8*(1), 1–3.

Garber, A. M., & Phelps, C. E. (1997). Economic foundations of cost-effectiveness analysis. *Journal of Health Economics*, *16*(1), 1–31.

Garen, J. (1984). The returns to schooling: A selectivity bias approach with a continuous choice variable. *Econometrica*, *52*(5), 1199–1218.

Giaccotto, C., Santerre, R. E., & Vernon, J. A. (2005). Drug prices and research and development investment behavior in the pharmaceutical industry. *Journal of Law and Economics*, *48*(1), 195–214.

Ginarte, J. C., & Park, W. G. (1997). Determinants of patent rights: A cross-national study. *Research Policy*, *26*(3), 283–301.

Global Insight (2007, May 30). Breakthrough for UCB as Xyzall finally approved by US FDA. URL. http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=106598036 Last accessed on April 27th 2011.

Goldberg, P. K., & Verboven, F. (2001). The evolution of price dispersion in the European car market. *The Review of Economic Studies*, *68*(4), 811–848.

Golder, P. N., & Tellis, G. J. (1993). Pioneer advantage: Marketing logic or marketing legend? *Journal of Marketing Research*, *30*(2), 158–170.

Grabowski, H. G., & Kyle, M. K. (2007). Generic competition and market exclusivity periods in pharmaceuticals. *Managerial and Decision Economics*, *28*(4–5), 491–502.

Gregson, N., Sparrowhawk, K., Mauskopf, J., & Paul, J. (2005). Pricing medicines: Theory and practice, challenges and opportunities. *Nature Reviews*, *4*, 121–130.

Heuer, A., Mejer, M., & Neuhaus, J. (2007). *The national regulation of pharmaceutical markets and the timing of new drug launches in Europe.* Kiel advanced studies Working paper 437. Kiel, Germany: Kiel Institute for the World Economy.

Hofstede, G. (1980). *Culture's consequences: International differences in work-related values.* Beverly Hills, CA: Sage.

Hofstede, G. (2001). *Culture's consequences: Comparing values, behaviors, institutions, and organizations across nations* (2nd ed.). Thousand Oaks, CA: Sage Publications.

Hultink, E. J., Griffin, A., Robben, H. S. J., & Hart, S. (1998). In search of generic launch strategies for new products. *International Journal of Research in Marketing*, *15*(3), 269–285.

Hunter, D. (2005). *Guaranteed future pain and suffering: The recent research on drug price controls.* WebMemo No. 908.
Huttin, C. (1999). Drug price divergence in Europe: Regulatory aspects. *Health Affairs*, *18*(3), 245–249.
Jack, A. (2007, April 18). *Companies international: Cautious drug makers delay launches. Financial Times.*
Jacobzone, S. (2000). *Pharmaceutical policies in OECD countries: Reconciling social and industrial goals.* OECD Labour Market and Social Policy - Occasional papers 40. Paris, France: OECD.
Kalish, S., Mahajan, V., & Muller, E. (1995). Waterfall and sprinkler new-product strategies in competitive global markets. *International Journal of Research in Marketing*, *12*(2), 105–119.
Kanavos, P. (2001). *Overview of pharmaceutical pricing and reimbursement regulation in Europe. Working paper.* London, UK: LSE Health.
Kyle, M. K. (2006). The role of firm characteristics in pharmaceutical product launches. *The RAND Journal of Economics*, *73*(3), 602–618.
Kyle, M. K. (2007). Pharmaceutical price controls and entry strategies. *The Review of Economics and Statistics*, *89*(1), 88–99.
Lanjouw, J. O. (2005). *Patents, price controls and access to new drugs: How policy affects global market entry.* NBER, Cambridge, MA: NBER Working paper 11321.
Libai, B., Muller, E., & Peres, R. (2005). The role of seeding in multi-market entry. *International Journal of Research in Marketing*, *22*(4), 375–393.
Lu, Z. J., & Comanor, W. S. (1998). Strategic pricing of new pharmaceuticals. *The Review of Economics and Statistics*, *80*(1), 108–118.
McAlister, L., Bazerman, M. H., & Fader, P. (1986). Power and goal-setting in channel negotiations. *Journal of Marketing Research*, *23*(3), 228–236.
Morton, F. M. S. (1999). Entry decisions in the generic pharmaceutical industry. *The RAND Journal of Economics*, *30*(3), 421–440.
Mossialos, E., Mrazek, M., & Walley, T. (2004). *Regulating pharmaceuticals in Europe: Striving for efficiency, equity and quality.* Berkshire, England: Open University Press for the World Health Organization on behalf of the European Observatory on Health Systems and Policies.
Novartis (2004, June 21). *Pricing and reimbursement of pharmaceuticals.* Company Report.
Park, W. G., & Wagh, S. (2000). Index of Patent Rights. *Economic Freedom of the World Annual Report.* Vancouver, BC: Fraser Institute.
Petrin, A., & Train, K. (2010). A control function approach to endogeneity in consumer choice models. *Journal of Marketing Research*, *47*(1), 3–13.
PhRMA (2004). *Foreign government pharmaceutical price and access controls.* Submission by the Pharmaceutical Research and Manufacturers of America to the US Department of Commerce.
Rapp, R. T., & Lloyd, A. (1994). "Civilized" pharmaceutical price regulations: Can the US have it too? *Regulation*, *17*(2), 72–82.
Ridley, D. B. (2007). International price comparisons for novel and follow-on drugs. *Value in Health*, *10*(6), 510–511.
Rojas, M. (2009). Price discrimination by pharmaceutical companies across Central American countries. *International Journal of Pharmaceutical and Healthcare Marketing*, *3*(2), 118–136.
Shankar, V., Carpenter, G. S., & Krishnamurthi, L. (1998). Late mover advantage: How innovative late entrants outsell pioneers. *Journal of Marketing Research*, *35*(1), 54–70.
Shankar, V., Carpenter, G. S., & Krishnamurthi, L. (1999). The advantages of entry in the growth stage of the product life cycle: An empirical analysis. *Journal of Marketing Research*, *36*(2), 269–276.
Sietsema, W. K. (2006). Product pipelines and pharmaceutical risk management in the new era of strict regulatory scrutiny. *International Journal of Pharmaceutical Medicine*, *20*(2), 99–106.
Sood, A., & Stremersch, S. (2010). *Deviation among technology reviews: An informative enrichment of technology evolution theory for marketing.* ERIM Report Series Reference Number ERS-2010-005-MKT.
Stremersch, S. (2008). Health and marketing: The emergence of a new field of research. *International Journal of Research in Marketing*, *25(Special Issue)*, 229–233.
Stremersch, S., & Lemmens, A. (2009). Sales growth of new pharmaceuticals across the globe: The role of regulatory regimes. *Marketing Science*, *28*(4), 690–718.
Stremersch, S., & Tellis, G. J. (2004). Understanding and managing growth of new products. *International Journal of Research in Marketing*, *21*(4), 421–438.
Stremersch, S., & Van Dyck, W. (2009). Marketing of the life sciences: A new framework and research agenda for a nascent field. *The Journal of Marketing*, *73*(4), 4–30.
Tellis, G. J., Stremersch, S., & Yin, E. (2003). The international takeoff of new products: The role of economics, culture, and country innovativeness. *Marketing Science*, *22*(2), 188–208.
Urban, G. L., & Hauser, J. R. (1993). *Design and marketing of new products.* Englewood Cliffs, NJ: Prentice-Hall.
Urch (2001). *Global pharmaceutical pricing: Strategic issues and pharmaceutical guidelines.* London, UK: Urch Publishing Ltd.
Urch (2001). *Emerging pharmaceutical markets: Potential and problems.* London, UK: Urch Publishing Ltd.
Urch (2002). *The pharmaceutical pricing and reimbursement systems of Central and Eastern Europe.* London, UK: Urch Publishing Ltd.
Urch (2005). *The guide to pharmaceutical pricing and reimbursement systems: Western Europe.* London, UK: Urch Publishing Ltd.
Vakratsas, D., & Kolsarici, C. (2008). A dual-market diffusion model for a new prescription pharmaceutical. *International Journal of Research in Marketing*, *25*(4), 282–293.
Vella, F. (1993). A simple estimator for simultaneous models with censored endogenous regressors. *International Economic Review*, *34*(2), 441–457.
Vernon, J. A., Golec, J. H., & Keener Hughen, W. (2006). The economics of pharmaceutical price regulation and importation: Refocusing the debate. *American Journal of Law & Medicine*, *32*(2–3), 175–192.
Wagner, J. L., & McCarthy, E. (2004). International differences in drug prices. *Annual Review of Public Health*, *25*(1), 475–495.
Weber, B. A., Roberts, B. L., & McDougall, G. J., Jr. (2000). Exploring the efficacy of support groups for men with prostate cancer. *Geriatric Nursing*, *21*(5), 250–253.
Wilking, N., & Jönsson, B. (2005). *A pan European comparison regarding patient access to cancer drugs.* Karolinska Institutet in collaboration with Stockholm School of Economics, Stockholm Sweden.
Wooldridge, J. (2002). *Econometric Analysis of Cross-Section and Panel Data.* Cambridge, MA: MIT Press.
Wuyts, S., Dutta, S., & Stremersch, S. (2004). Portfolios of interfirm agreements in technology-intensive markets: Consequences for innovation and profitability. *The Journal of Marketing*, *68*(2), 88–100.