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European market-entry
strategies for
generics companies
A “generic” approach
will not work

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Executive summary

Generics manufacturers may have an opportunity to expand and grow in Europe, but identifying a winning formula for market entry poses challenges for many small and mid-size companies.

Because each European country's market dynamics, regulatory requirements, patient attitudes, and prescribing habits are complex and unique, Deloitte research suggests that the leading go-to-market strategy for generics manufacturers is neither "one-size-fits-all" nor even "one-size-fits-many." Rather, manufacturers should consider devising country-specific approaches based on three "hows" that can help them understand market dynamics and identify the capabilities they need to be effective:

- How are generics prescribed?
- How are generics dispensed?
- How are generics purchased?

This paper summarizes attributes that can be used to distinguish select European countries—specifically, the EU5 (European Union countries of France, Germany, Italy, Spain, and the UK) and representative Eastern Europe markets Poland and Russia—and creates a baseline for market assessments and potential entry strategies—build, buy, or partner—that small and mid-size generics companies may use to set the stage for sustainable growth.



Introduction

Following the financial crisis of 2008, many European countries instituted new austerity programs that included expanding the use of generic drugs as a way to manage health care costs. These programs heralded a potential generics industry boom in Europe, and today generic drugs account for around 50 percent of the European market by volume.¹ However, deeper analysis paints a more nuanced and complex picture of the European generics landscape with significant differences in generic adoption and usage. While certain markets experienced impressive growth over the last several years (e.g., Spain, Ireland, and France), other markets remained flat or even shrank (e.g., United Kingdom and Germany). Further, an analysis of generics volume penetration levels across selected European countries shows a generally fragmented landscape with few commonalities.²

Based on these macro-level observations and discussions with commercial strategy leaders at generics companies, Deloitte took a closer look at the European generics market and developed considerations for small-to-mid-size companies seeking to successfully develop and implement an effective market-entry strategy.

Our examination yielded an important observation: There is not one European generics market; there are 28 unique European generics markets. As a result, the concept of a “generics market-entry strategy for Europe” is complex and requires a detailed, country-by-country analysis because each has a unique health care system, regulatory requirements, prescribing habits, and patient attitudes towards health care. A generics company’s selected market-entry strategy, therefore, will depend on how the company is differentiated in each targeted country with respect to its product portfolio, internal capabilities, and appetite for risk. In addition, a company should consider pricing and parallel trade/importation dependencies across European countries, which may have ramifications for market-entry sequencing.

This paper summarizes the attributes that can be used to distinguish select European countries—specifically, the EU5 (France, Germany, Italy, Spain, and the UK) and

representative Eastern Europe markets Poland and Russia—and creates a baseline for market assessments that small and mid-size generics companies can use to develop their entry strategies. To facilitate a broad understanding of the dynamics at play we analyzed conditions in seven of the largest and most diverse European markets. Based on the attributes of these seven markets, we discuss potential entry strategies—build, buy, or partner—that generics companies may use to set the stage for sustainable growth.

European generics market overview

Generic drugs comprised around 50 percent of all medicines dispensed in the European Union (EU) in 2014, but that rate was not consistent across countries in the EU.³

Germany was the largest European country in terms of generics value in 2014 (35 percent of global generics sales value) whereas other countries experienced much lower percentages by value (for example, around 10 percent in Italy). Generics volume penetration was also highest in Germany, where rates have steadied between 2008 and 2015 at approximately 75 percent across all medicine types. Interestingly, Poland and the United Kingdom were tied at second and Russia at third in terms of generics volume penetration.⁴ Each of those four countries—Germany, Poland, the United Kingdom, and Russia—have greater generics volume penetration than the EU average.⁵

Two overarching trends are creating disruption in the European generics industry: the fast-paced commoditization of generic versions of primary-care products and a pronounced increase in the number of specialty drugs and biologics products losing patent protection. These trends indicate that generics market entrants with truly differentiated products in areas of high unmet need should be able to effectively enter new markets and thrive.

Assessing the complex European generics market calls for a detailed examination of each country’s unique attributes based on “three hows:” How are generics prescribed? How are generics dispensed? How are generics purchased?

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When larger pharmacy chains dominate a market, the importance of large wholesalers and distributors on generic sales tends to increase, with supply chain flexibility and efficiency often cited as key capabilities during manufacturer contracting and partner selection.

How are generics prescribed?

This question does not focus on who prescribes generics, but rather, it focuses on how generic prescriptions are written—either using the International Non-Propriety Name (INN) or specific generic brand name. There is clear differentiation in European markets as to whether INN generic prescriptions or branded prescriptions are more commonly prescribed. When physicians write prescriptions using generic brand names it implies that brand perception, both at the company/manufacturer and product levels, is a key sales driver. In contrast, when physicians write prescriptions in INN, they do not have much influence on product selection, so price—wholesale and retail—is a primary strategic driver. Price-driven markets typically require manufacturing capabilities that enable low production costs, whereas brand-driven markets typically require strong customer service capabilities and local sales forces. By changing the prescribing regulations in some European countries to encourage generics consumption, governments have also shifted the capabilities needed for companies to compete in those markets.

How are generics dispensed?

This question focuses on a market's supply chain requirements as well as non-physician influencers. We found that in general, the scale of the dispensing pharmacy is a market differentiator. Generics are either dispensed at smaller-scale, independent pharmacies (e.g., in Italy and Spain) or at larger chains that are either independent or a part of another entity, such as a supermarket (e.g., in the United Kingdom). Government regulation may also limit the degree of pharmacist influence; in Germany and France, laws prohibit one pharmacist from owning more than a few pharmacies.⁶

When larger pharmacy chains dominate a market, the importance of large wholesalers and distributors on generic sales tends to increase, with supply chain flexibility and efficiency often cited as key capabilities during manufacturer contracting and partner selection. When individual pharmacies dominate the landscape, having an expansive distribution network and sales force are typically key. Building and maintaining pharmacy relationships are especially important in INN-prescribing markets where pharmacy owners' stocking decisions directly drive product sales.

How are generics purchased?

Whether or not generics are purchased through a tendering process is the final question when developing a market profile. Tendering is a purchaser cost-control mechanism aimed at lowering unit prices. The process is becoming more popular among large payers and hospitals (e.g., Germany's AOK national tender, regional payers in Italy and Spain). The potential downside of tendering is that its thinner margins are likely not attractive to incumbents or newcomers. However, the upside of tender-heavy markets for newcomers tends to be expedited market entry and access. If a company's competitive advantages are low production costs and stable supply chain, then tender-heavy markets could be the first entry points to establish a European presence.

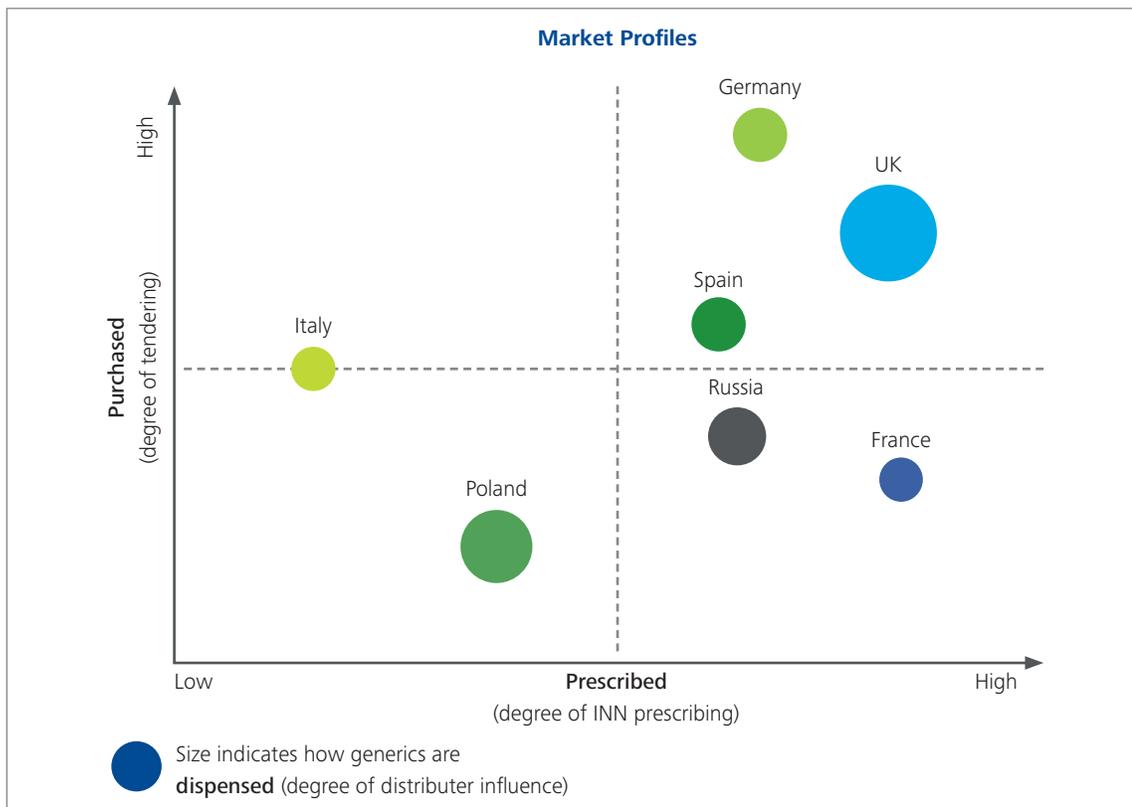
Assess each market

To help determine optimal European entry points, a generics company should compile individual market profiles to understand their specific value drivers and dynamics. Since this can be a large undertaking—Europe has nearly 30 distinct markets—a company should first assess markets in which it has existing connections, such as manufacturing plants or distributor agreements.

When assessing the EU5, Poland and Russia (see Appendix for individual market profiles) the recurring themes of price competition, local relationships, and risk levels indicate which capabilities may be table-stakes for entering a particular market. These general themes also help to cluster countries with similar characteristics (Figure 1):

- United Kingdom and Germany: Companies compete on price and rely on broad portfolios to gain greater market influence. Portfolio breadth and channel/wholesaler access are key capabilities.
- Italy, Spain, and France: Local relationships are important, as physicians, pharmacists, and regulators have significant influence in how generics reach patients. Marketing and brand-building (especially at the product level) are key capabilities.
- Poland (mature market) and Russia (emerging market): Potential risks and government pressures are typically greater for companies seeking to establish a local manufacturing and economic footprint. Brand-building capabilities are important, with an emphasis on the company’s local reputation (i.e., manufacturing and economic impact).

Figure 1.



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A combined view of European market characteristics based on the “three hows” shows the critical success factors generics companies should consider when evaluating their capabilities and formulating single market-entry strategies (Figure 2).

Figure 2.
Snapshot of key European markets

	Italy	Spain	France	UK	Germany	Poland	Russia
Prescribed	Branded Generics	INN prescribing requirement	INN prescribing favored	Mostly INN Prescribing	INN prescribing favored	INN prescribing encouraged	INN prescribing requirement
Dispensed	Heavy local pharmacist influence	Same ingredient INN substitution	Pharmacist substitution targets	Wholesaler/ pharmacy chain influence	Insurance fund (A OK) influence	Large distributor influence	Chain pharmacy influence
Purchased	Provincial tendering systems	Beginnings of tendering system	Heavy government role	Heavy government discount rate	Tendering system	Government reimbursement caps	Tendering system and private market
Critical Success Factors	<ul style="list-style-type: none"> • Product brand recognition • Local sales force • Distributor relationship 	<ul style="list-style-type: none"> • Regulatory/political experience • Stable supplies • Distributor relationship 	<ul style="list-style-type: none"> • Regulatory/political experience • Local sales force • Flexible supply to pharmacy 	<ul style="list-style-type: none"> • Low cost of production • Breadth of portfolio • Flexible supply in the retail market 	<ul style="list-style-type: none"> • Low cost of production • Breadth of portfolio • Stable supplies 	<ul style="list-style-type: none"> • Product brand recognition • Local sales force • Distributor relationship 	<ul style="list-style-type: none"> • Product brand • Recognition • Local sales force • Regulatory/political experience

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Know and build on your strengths

In addition to assessing European market characteristics and capabilities critical to success, potential entrants should evaluate their core competencies in eight areas (Figure 3) to determine which ones they may leverage as competitive advantages in new markets.

Figure 3.



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Using the knowledge gained from weighing their competitive advantages against specific market characteristics may help generics companies determine not only where to play but also how to win. For example, identifying markets that would be receptive to a differentiated niche product or service may help to determine an initial entry point for that niche product and the subsequent opportunity to introduce additional products.

If a generics company's internal capabilities do not align with certain markets' critical capabilities for success, the company does not necessarily have to eliminate that market from consideration—a capability gap analysis can help to address what additional/new capabilities are needed. To fill those gaps, companies have the option to partner, buy, or build.



Partner: Generics companies can choose from a variety of partnership models, including joint ventures (JVs), strategic alliances, and licensing. A partnership can accelerate entry into a key market, help a company acquire valuable operational information, and mitigate risks.



Buy: Mergers and acquisitions (M&A) tend to have a higher risk level than partnerships but may accelerate the speed at which companies can grow in a new market. Buying may make sense when the core capabilities or access a company needs are capital-heavy, scale-driven, or market-specific.



Build: If a suitable acquisition target cannot be identified or additional economic factors create a case for in-house development, companies may decide to build needed capabilities rather than acquire them.

Case Study:

Cipla: From "partner" to "build"

Cipla is an \$8.4 billion Indian drug manufacturer with expertise in respiratory products. Traditionally, Cipla used strategic partnerships to gain sales and distribution capabilities in new markets. In Europe, for example, Cipla partnered with Swedish company Meda AB to market a nasal inhaler. However, Cipla's European growth was restricted by its partners' operational limitations.⁷

The prospect of a number of respiratory therapies coming off patent in the EU offered tremendous potential for revenue and market expansion and prompted Cipla in 2014 to switch from a "partner" to "build" market-entry model. The company built a captive sales force to support the launch of several respiratory drugs in mature European markets.⁸

In September 2014, Cipla launched Salmeterol/Fluticasone Metered Dose Inhaler (MDI) in Germany and Sweden using its in-house sales force.⁹ Since then, Cipla has further monetized this capability by offering to be the in-country partner to other companies. For example, Cipla partnered with S&D Pharma to market S&D's children's vaccinations within the EU market.¹⁰

Should you partner, buy, or build?

Companies evaluating which of the three market-entry options—partner, buy, build—will best meet their needs should consider each option’s potential influence on speed to entry, risk versus perceived return, and market specificity (Figure 4). The preferred strategy is likely to differ by country/market, and each selection should be re-evaluated periodically as a company expands its portfolio, adds capabilities, or moves into other markets.

Figure 4.

Consideration	Partner 	Buy 	Build 
Speed to entry	<ul style="list-style-type: none"> If speed is critical to “winning” in the market, companies with proven market capabilities can accelerate entry 	<ul style="list-style-type: none"> If asset-intensive capabilities are sought (i.e., manufacturing or distribution), acquiring is quicker than building Acquisition can accelerate pace and scale of vertically-integrated capabilities (i.e., distribution capabilities) 	<ul style="list-style-type: none"> Asset-intensive capabilities may have a longer time horizon; of critical for entry, may delay entry Previous success (or lack of) in building similar capabilities will influence feasibility and level of comfort
Risk vs. Perceived return	<ul style="list-style-type: none"> Partnering allows companies to gain market and operational know-how to offset risk of new-to-you market Companies should buffer risk in an immature and/or untested market where returns are not certain 	<ul style="list-style-type: none"> When done correctly, it is more profitable and returns more value to shareholders than internal growth Risk should be carefully managed to meet synergy expectations 	<ul style="list-style-type: none"> Higher perceived returns justify the risk of not partnering Capabilities built can be transferred to other markets
Market specificity	<ul style="list-style-type: none"> Ability to leverage local brand is important to success The capability sought is specific to a local market and not easily transferred to other markets 	<ul style="list-style-type: none"> Ability to leverage local brand is important to success and is strategically important to have ownership of that brand The complementary nature of the union creates capabilities that can be scaled across therapeutic areas or geographies 	<ul style="list-style-type: none"> If what you are building is a critical capability for success in the market, there is a strong strategic reason to have ownership and control over this capability The capability can be scaled across geography and/or to gain depth in a market

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Case Study:

MercuryPharma and Amdipharma: Merging complementary assets

The merger of MercuryPharma and Amdipharma illustrates how the right acquisition can help accelerate market entry across Europe. In 2012 MercuryPharma was a \$700 million company with a niche product portfolio. Contract manufacturing enabled MercuryPharma to keep its fixed costs low, resulting in little competition from branded and large generic pharmaceutical companies in the price-sensitive U.K. market, which generated 80 percent of its sales.¹¹ However, MercuryPharma had limited penetration in other markets.

Amdipharma offered a diverse portfolio of specialty off-patent products of a different type than MercuryPharma, as well as a geographic presence in more than 80 countries. Only 34 percent of Amdipharma’s revenue was generated in the United Kingdom. Amdipharma also used a contract manufacturing model to limit physical assets and keep costs low.¹²

Merging MercuryPharma’s and Amdipharma’s complementary product and geographic assets produced a flexible, price-focused company that does not compete directly with branded and large generic pharmaceutical companies.¹³

Sequencing matters

Regardless of how and which European market(s) a generics company decides to enter, the sequence in which it does so should be a careful consideration because there are cross-country dependencies that may impact pricing and distribution decisions. For example, different pricing mechanisms in EU countries may result in different sale prices for the same generic drug. Countries using tender procurement typically set a generic's price based on supplier input. Other countries may use a reference price, such as a percentage discount off of the original innovator drug, to determine a generic's price. In these markets, the innovator company typically has more control over generic pricing—in France, drug manufacturers are involved in pricing negotiations and can even lower the price for their drugs to force a generics company to enter the market at an even lower, undesirable price.¹⁹ This could reduce the generic company's overall pricing power—if it tries to enter a different market at a higher price point, the local health authority may ask the company to sell at the lower price point it offered in France.

Generics companies also should consider the potential advantages and risks of parallel trade/importation, which enables the free movement of pharmaceuticals among higher-value and lower-value European markets.

Generics companies also should consider the potential advantages and risks of parallel trade/importation, which enables the free movement of pharmaceuticals among higher-value and lower-value European markets. One demonstrated benefit of parallel trade is that companies may use lack of supply to their advantage. If a drug is in short supply in one market, distributors may import the same drug from another market. A similar dynamic may play out with pricing by shifting drug volume to a market commanding a higher price. Taking advantage of parallel importation is typically not a costly process, as it often requires only relabeling the packaging and modifying the product insert to meet the requirements of the destination country.

Conversely, one potential risk of parallel importation is negative brand association. For example, in some countries (e.g., the United Kingdom), distributors often increase prices during shortages. Even if a generics company does not sell in that market, the company's reputation may be associated with the mark-ups. To help offset the inflated prices, health authorities can solicit a company to enter the market and eliminate the distributor parallel import through increased volume. Even if the company had decided not to enter that market, pressure from the health authority would overrule that decision.

Moving from market entry to sustainable growth

Conducting a market assessment and developing a targeted entry strategy are crucial first steps for a generics company seeking to establish or expand its presence in Europe. However, this process does not necessarily support sustainable growth. Once a company has successfully entered a market and established its presence there, it should assess whether it has achieved its short-term (e.g., six-month) strategic, financial, and operational goals by tracking and analyzing predefined metrics or key performance indicators (KPIs). While specific KPIs will vary by company, they typically measure, among other things, profitability (both from a revenue growth and cost management perspective), risk management effectiveness, and whether the market strategy and brand positioning are compatible with the broader corporate strategy. If the company is not achieving its short-term objectives, it should consider reconfiguring operations or revising its market strategy.

Case Study:

Dr. Reddy in Germany: Shifting market, changing strategy

In 2006, Dr. Reddy's Laboratories (DRL) acquired Betapharm, the fourth-largest generics company in Germany.¹⁴ DRL anticipated that the benefits of gaining access to this market and leveraging Betapharm's strong brand and distribution network outweighed the potential risks of a full-scale market entry, even though DRL had no existing footprint there.¹⁵ However, shortly after the acquisition, the German government dramatically changed its policy to source from low-cost vendors through a tender-driven system.¹⁶ This regulatory change dramatically altered market success factors and DRL found itself operating in a cost-driven market. Despite implementing a variety of cost-reduction initiatives, the merger's viability came into question. In 2013, DRL announced a turnaround strategy focused on adding value through innovation and launching products outside of the tender system.¹⁷ The company is investing in R&D and manufacturing capabilities to reinforce this strategic choice and is currently co-developing oncology biosimilar drugs with partners.¹⁸

Appendix

Market profiles

France

Heavy government influence

The French generics market is 31 percent by volume with the top players dominating.²⁰ The government plays a large role in approving and setting prices for generics, which are generally not as profitable as in other European countries.²¹

- **Prescribed:** Physicians use INN prescribing, which became mandatory in January 2015. There are penalties and bonuses for reimbursement.²²
- **Dispensed:** Pharmacies are independently owned by pharmacists, and regulations prevent individuals from owning more than three pharmacies. Targets have been introduced for pharmacists to meet generics substitution by medicine type.²³ Additionally, there are incentives for pharmacists to substitute generics if manufacturers offer significant discount rates that result in prices lower than those specified by the government.
- **Purchased:** A tender system is only applicable for the hospital market, and while tendering does not seem to be a large contributor to generics sales, the national government plays a large role in setting reimbursement rates and approving allowable therapeutic areas for which generics can be substituted.²⁴

Germany

High penetration, fierce competition

Within the EU, Germany is a relatively mature generics drug market with penetration at 75 percent by volume and 35 percent by value.²⁵ From a regulatory and reimbursement perspective, the market driven by tenders, with price and quality considered key criteria. The proliferation of generics companies in Germany contributes to fierce competition and pricing pressures.

- **Prescribed:** Physicians are not required to prescribe by INN but may choose to avoid substitution by prescribing brands. Despite this, physician budgets and IT systems encourage generics INN prescribing.²⁶

- **Dispensed:** Distributors and pharmacies have limited power, as the majority of drugs are tendered and selected by Germany's largest health insurance funds, AOK, BKK, IKK, VdeK. Pharmacists are required to use generic substitutes (i.e., one of the three cheapest medicines), unless substitution is forbidden by a physician.²⁷ Pharmacies are independently owned, and regulations prohibit ownership of more than four pharmacies.
- **Purchased:** Reimbursement is primarily driven by tenders, which cover 60-70 percent of drugs.²⁸

Italy

Independent pharmacies' influence

Italy has one of the smallest generics markets in the EU5, with 25 percent penetration by volume and 10.4 percent by value.²⁹ Italy has been slow to adopt generics for a number of reasons, including extended patent protection, relatively low brand-name drug prices, and requirements for price and reimbursement approvals under a national health system structured under disparate, provincial authorities.³⁰

- **Prescribed:** Branded generics marketed by established and trusted local players dominate the market, so using a local sales force to develop and maintain physician relationships may be critical to success.³¹
- **Dispensed:** Although generics substitution is mandatory, pharmacists decide which medicines are dispensed if not dictated by the physician. Pharmacists, who tend to operate individual pharmacies, have financial incentives to dispense branded generics medicines based on higher discount rates for higher-priced medicines.³² Large generics companies in Italy generally focus on influencing pharmacists more than physicians.
- **Purchased:** Despite national oversight, local health authorities have autonomy and can introduce tendering systems.³³ This provincial authority adds to the complexity of market entry, making it critical that companies understand and are able to navigate Italy's complex regulatory environment.

Spain

Regulatory and market dynamics

Recent legislation to move to INN prescribing and substitution is changing the generics landscape in Spain.³⁴ As of 2013 the market was 18.5 percent by value and 40 percent by volume.³⁵ Spain's generics market is dominated by local companies but as the government takes a more active role in mandating how generics are prescribed, and if tendering systems are used, the competitive landscape is expected to evolve.³⁶

- **Prescribed:** Since physicians are now required to prescribe medicines using INN, using a local sales force is generally becoming less important. Companies with broad portfolios that can compete on price should benefit from INN prescribing.
- **Dispensed:** With INN prescriptions, pharmacists can dispense any generics with the same ingredient,³⁷ shifting the focus to financial margins.
- **Purchased:** A tendering system instituted in Andalucía. Thus far it has been having limited success due to significant stock-outs and supply chain issues. While the central government has expressed opposition, it seems that additional regions in Spain will emulate these tendering systems.³⁸

United Kingdom

Price competition key

The United Kingdom is generally regarded as a good entry point into Europe, given its high generics penetration—70 percent by volume—low barriers to entry, and relatively straightforward entry requirements.³⁹ However, being successful in the United Kingdom can be difficult, as the market is dominated by INN unbranded generics. This offers limited opportunities to differentiate by product or company brand, thereby driving manufacturers to compete almost solely on price.⁴⁰

- **Prescribed:** While physicians are not obligated to prescribe by INN, 82 percent of all prescription items were prescribed by INN in England since 2008.⁴¹
- **Dispensed:** The intermediaries controlling drug distribution are generally pharmacy chains and large wholesalers/distributors. (The top three control nearly 75 percent of the market.)⁴²
- **Purchased:** While tenders exist, pricing is driven by supply and demand with some indirect pricing control from the government. Although the list price may look attractive, generally the net price is discounted 80 percent, with rebate discounts going to the National Health Authorities and wholesalers.⁴³



Poland

Mature market, local manufacturers

Poland is generally considered to be a mature market, with generics around for more than 10 years.⁴⁴ Poland's generics penetration is one of the highest in Europe, at 70 percent by volume and 55 percent by value.⁴⁵ Additionally, local manufacturers hold nearly 70 percent market share.⁴⁶

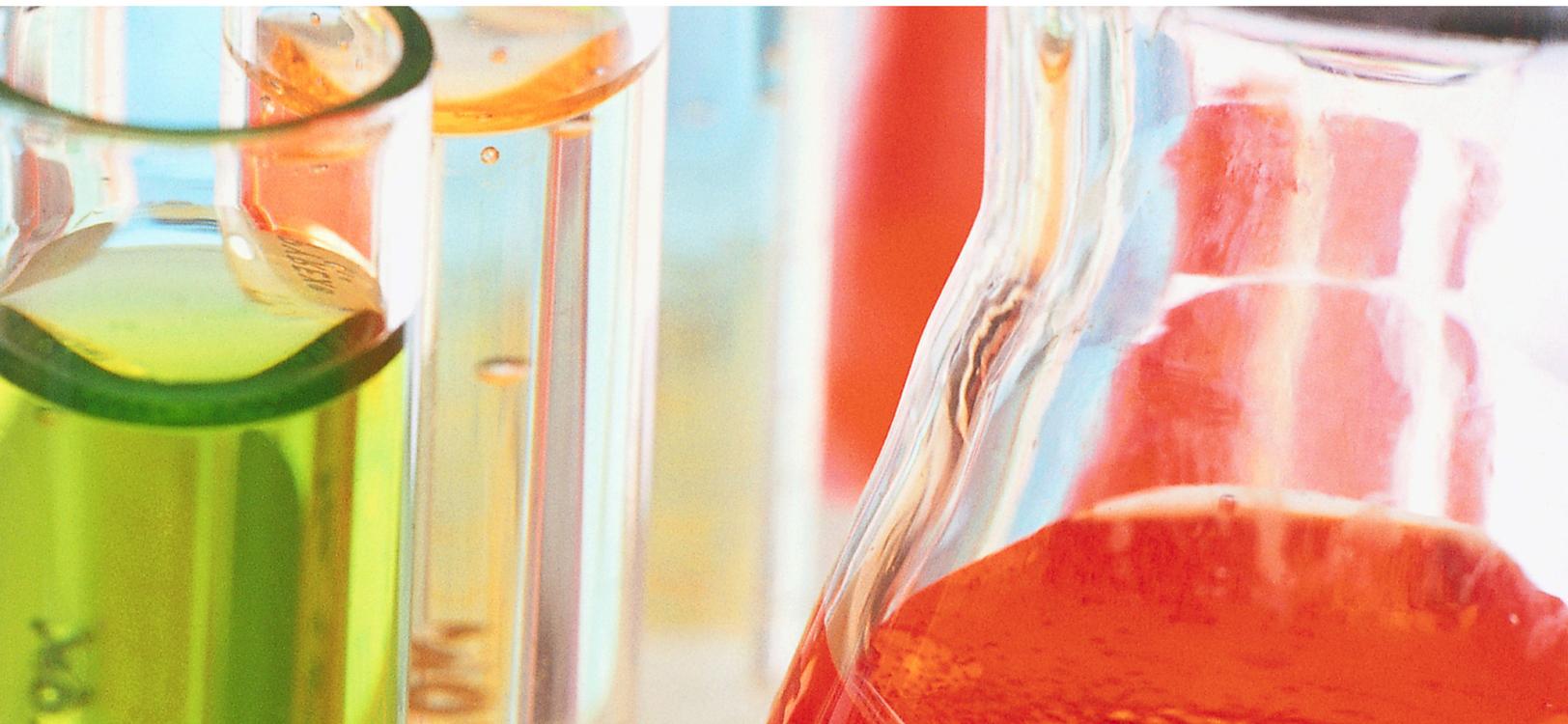
- **Prescribed:** Physicians are not obligated to prescribe by INN but are encouraged to do so. Branding is a significant influencer on physicians and patients.
- **Dispensed:** Poland's generics distribution channel is highly concentrated, with the top five distributors controlling 80 percent of the market. At the pharmacy level, generics substitution is not obligatory; however, pharmacists are permitted to substitute for the same molecule in the same therapeutic class.⁴⁷
- **Purchased:** In 2011 the government cap on Poland's drug reimbursement budget decreased from 21 percent to 17 percent. As a result, patients' share of the treatment cost is higher, with co-payment generally around 33 percent—even higher for OTC products.⁴⁸

Russia

Local operations requirement

Generics represent approximately 51 percent of Russia's drug market by volume.⁴⁹ The market historically has been dominated by local manufacturers. In recent years, though, demand for branded generics has increased and multinationals have invested in the country by establishing manufacturing facilities there. Furthermore, Russia has introduced a series of measures to restrict access to state tenders for imported medicines to further stimulate domestic manufacturing, and to make local manufacturing and local clinical studies "must haves."⁵⁰

- **Prescribed:** Starting November 1, 2013, physicians were required to use only INN prescribing.
- **Dispensed:** Russia is dominated by distributors and chain pharmacies; in recent times, consolidation has occurred among pharmacies.⁵¹
- **Purchased:** there are two paying markets in Russia: The state tenders/public market, which places tremendous pressure on product price; and the private market, in which consumers/patients pay out of pocket for medications.⁵²



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