

June 2015

# The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective



# Introduction

In the European Union (EU), where strained healthcare systems are facing ever greater demands from an ageing population, generic medicines have played a significant part in controlling costs. Off-patent medicines now account for 92% of the treatment volume in the region. And competition from generic medicines drives the cost of off-patent products down 61% from their cost during market exclusivity. This saved payers an estimated €100Bn in 2014 and has contributed to significantly higher access for patients in many countries, across many therapeutic areas.

However, over the next several years, the number of small molecule original brands losing their market exclusivity in Europe—and the savings opportunities to be had from generic medicines and the competition they create—will be dramatically reduced. What role, then, will generic medicines have in sustaining health systems in the EU?

To answer that question, the IMS Institute for Healthcare Informatics conducted research to understand current market trends and to quantify the full scope of generic medicines' contributions. The results of this research are reported here along with implications for various stakeholders invested in the long-term vitality of the region's healthcare system. Finally, the report recommends a course of action for policymakers in support of the role the generic medicines industry can play.

All research, interpretation and the development of this report was undertaken independently by the IMS Institute. Contributions from colleagues across IMS Health are gratefully acknowledged, including: Elena Klimova, Alan Sheppard and Per Troein.

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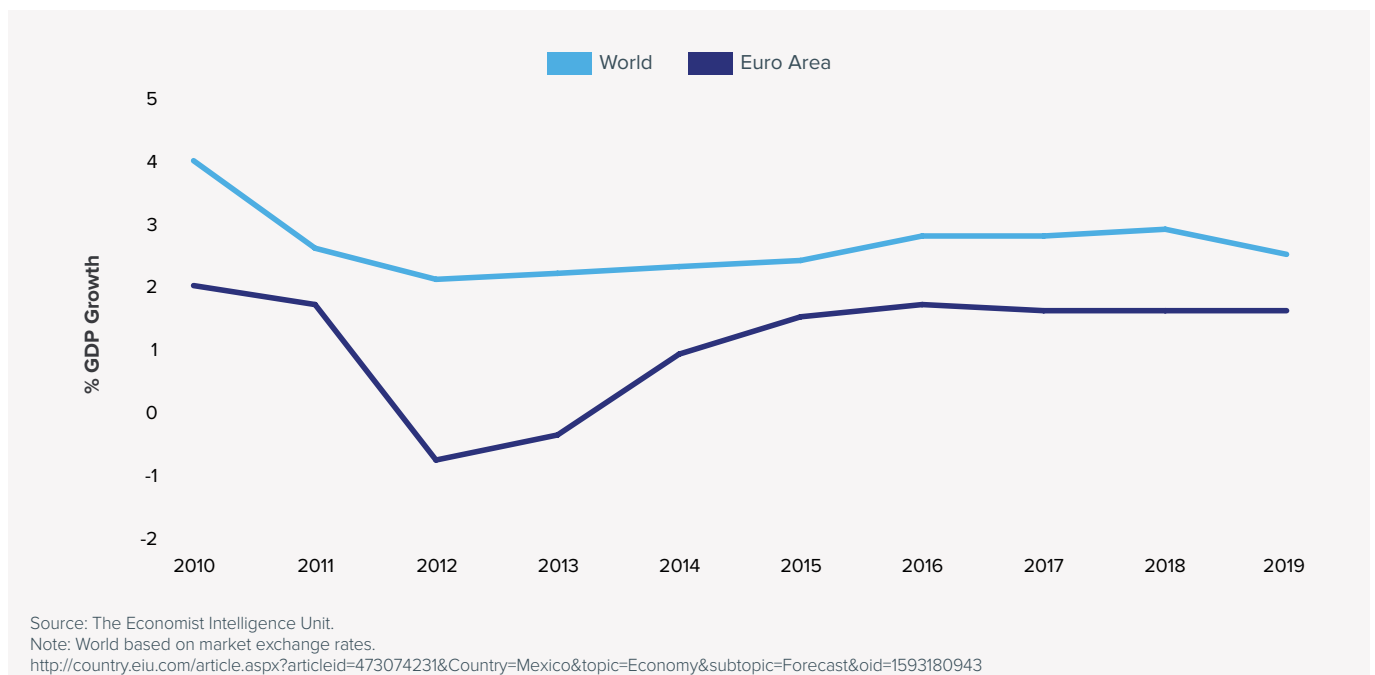
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# The Nature of the Challenge

## 1. Flat economic growth is forcing continued austerity measures

Providing affordable healthcare that meets acceptable standards is a major challenge in most European countries. Resources are pulled in many directions, and European economies struggle to raise sufficient funds from taxation to cover their budgets. The region's Gross Domestic Product (GDP) is forecasted to grow in the single digits at least to 2019 (see Exhibit 1).

Exhibit 1: Euro Area and World GDP % Growth Forecast



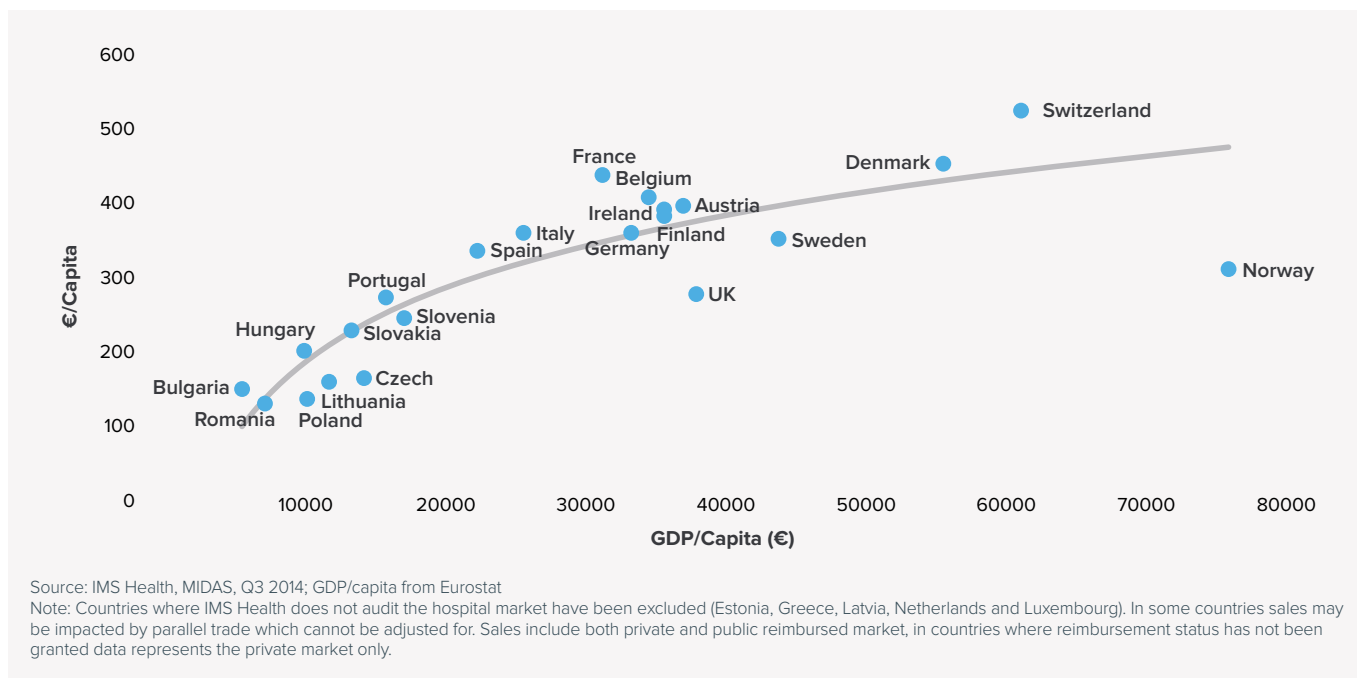
Public expenditure on healthcare in the EU reached an average of 8.7% of GDP in 2012, having increased from 5.7% in 1980.

On average, Western European countries spend 8 to 12 percent of their GDP on healthcare, a proportion that has remained stable despite increasing demand. The specific proportion of GDP spent on healthcare varies widely between Member States: it is above average in all Western European countries except Portugal (11% in Austria, Denmark, France, Germany, and the Netherlands); and below average in all Eastern European countries (6% in Estonia, Latvia, and Romania).<sup>1</sup>

Spending on pharmaceuticals, on average, accounted for almost a fifth of all healthcare expenditure across EU Member States in 2012, making it the third-largest spending component after inpatient and outpatient care. The economic crisis has had a significant effect on the growth in pharmaceutical spending in many European countries. Between 2000 and 2009, annual pharmaceutical expenditure per capita grew an average of 3.7% in real terms in EU Member States, but fell in the following three consecutive years. On average, pharmaceutical spending fell by over 2% per year in real terms between 2009 and 2012 across the EU.<sup>1</sup>

Pharmaceutical spending is closely related to GDP per capita and, over time, tends to follow GDP growth rather than population needs (see Exhibit 2). This means that many countries with low GDP have a risk of significant undersupply issues.

Exhibit 2: Pharmaceutical Spending vs. GDP/Capita by Country



In the ten years from 2005 to 2015, prescription volume in the EU increased more than 100 percent in seven key therapeutic areas.<sup>2</sup> Thus, lowering pharmaceutical costs is seen as an important element of achieving sustainable healthcare, and even before the recession, many European countries attempted to control pharmaceutical expenditures via a mix of price and volume controls directed at physicians and pharmacies. They also relied on policies targeting specific products. In Germany, pharmaceutical companies must now enter into rebate negotiations with health insurance funds for new innovative medicines, putting an end to the previous free-pricing regime. In 2011, Spain passed a law requiring physicians to use generic prescribing designed to save €2Bn a year. In France, price reductions or rebates on pharmaceuticals have often been used as adjustment variables to contain growth in health spending. Meanwhile, in the United Kingdom, the 2014 Pharmaceutical Price Regulation Scheme (PPRS) has been amended to ensure that expenditures on branded medicines remain flat for the next two years; if companies exceed their allowed growth rate, they must make rebates to the Department of Health.

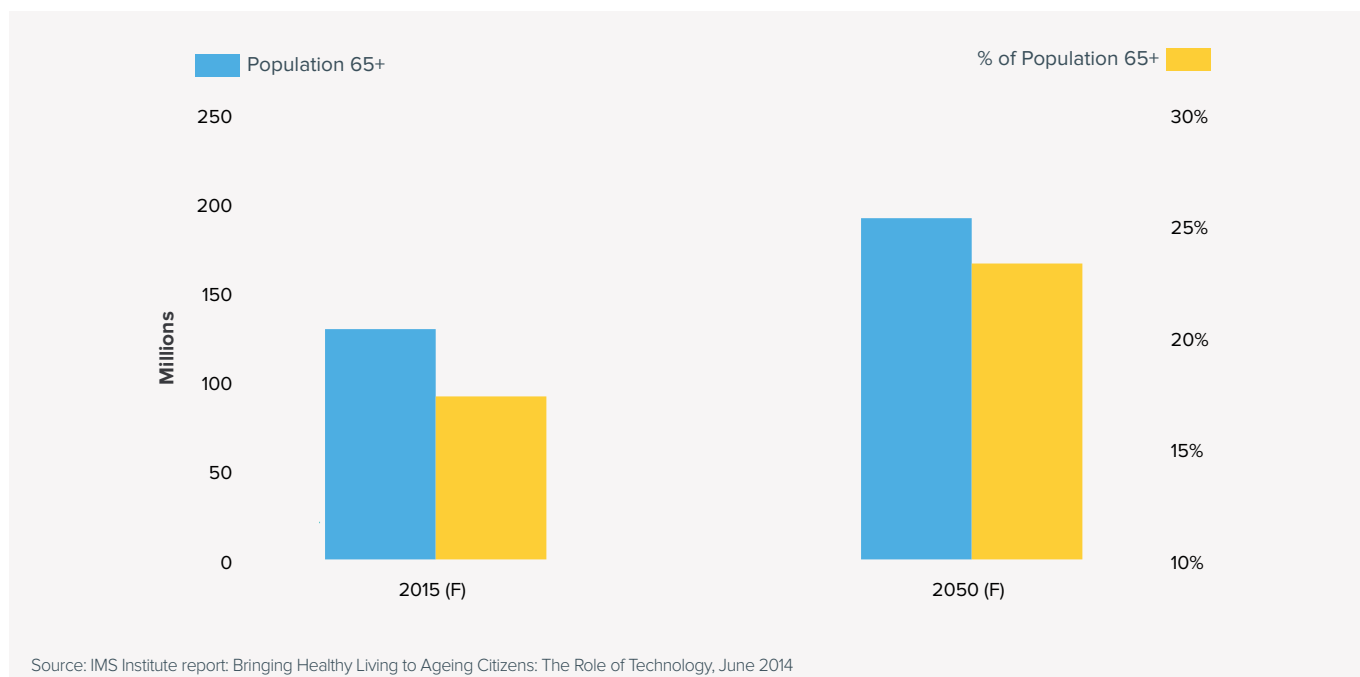
Many countries have started to shift healthcare costs to patients via co-payments, new reimbursement policies, and deregulation of certain therapies in order to reduce the burden on the provider. In the U.K., prescription fees have increased, and in France, products are being removed from the list of prescribable medicines. However, savings produced by all of these efforts can quickly be eradicated by changing demographics and the availability of new, more expensive medicines.

## 2. An ageing population—with the attendant chronic diseases—is increasing the demand for healthcare services

**Population ageing** is one of the greatest social and economic challenges for the European Union and is the result of low fertility rate, the gradual progress of baby boomers toward retirement age, and increased life expectancy at birth.

It is estimated that the proportion of people aged 65 years and older within the EU will grow from 129 million (17.3% of population) in 2015 to 191 million (23.3% of population) in 2050 (see Exhibit 3).<sup>3</sup>

**Exhibit 3: Europe Ageing Population Forecast to 2050**



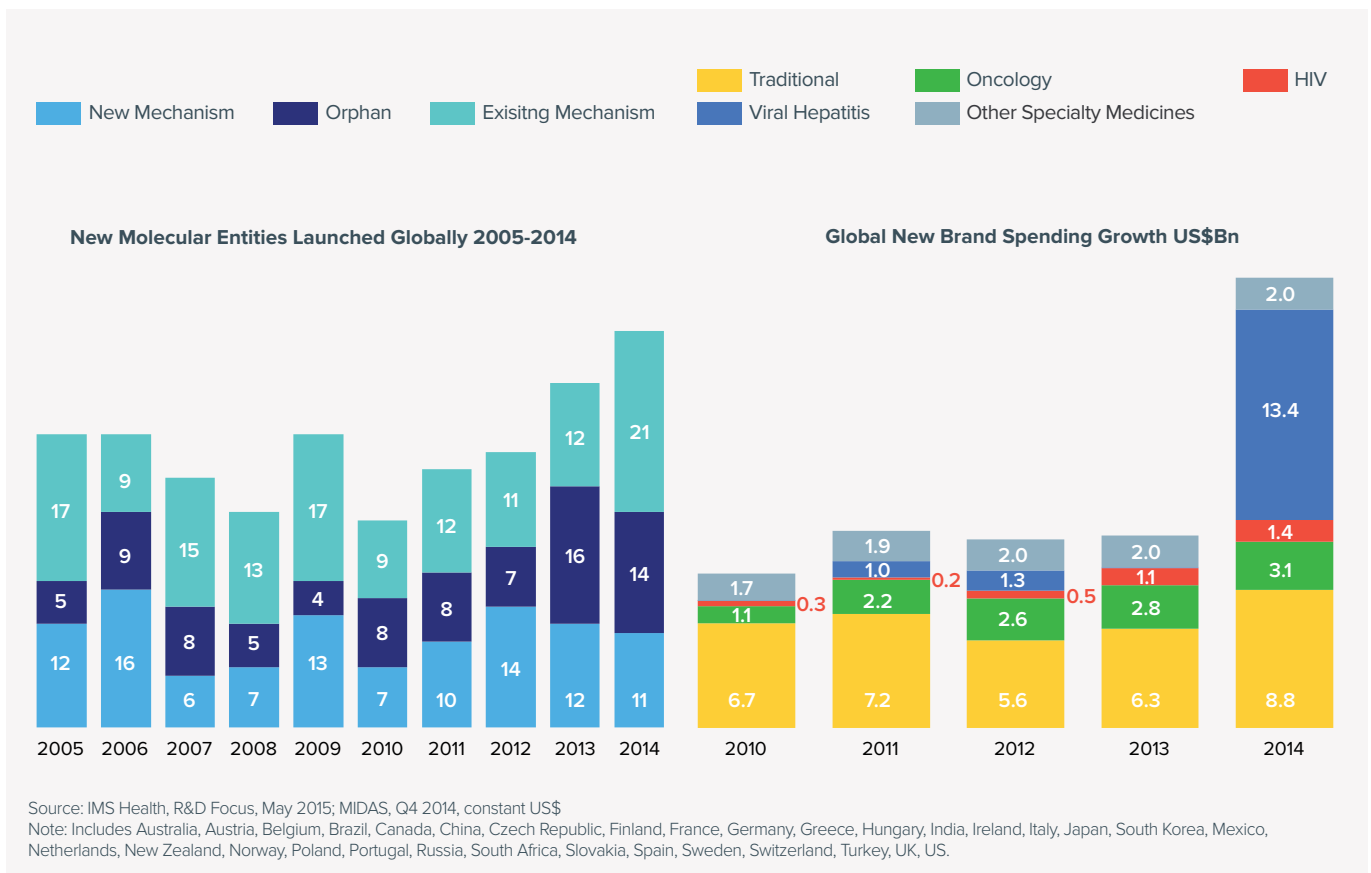
An ageing society and poor lifestyle are linked to chronic diseases and conditions that have traditionally included cardiovascular disease, diabetes, and asthma/COPD. As survival rates and durations have improved, many varieties of cancer, HIV/AIDS, mental disorders (such as depression, schizophrenia and dementia), and disabilities such as sight impairment and arthroses are all considered chronic conditions. Chronic diseases are now responsible for most of the disease and deaths in Europe. Expenditures on chronic care are rising across the region, consuming increasingly greater proportions of public and private budgets.<sup>4</sup>

An ageing population also has different healthcare requirements ranging from a higher demand for mental health care, to homecare and assistance, and social capital and self-management services.

3. A surge in innovation to meet unmet clinical needs is drawing heavily on healthcare budgets

**New diagnostic and treatment options** are improving survival rates for patients in many chronic diseases such as cancer, multiple sclerosis, rheumatoid arthritis and HIV/AIDS, and they are, in turn, driving demand for new medicines. Looking at the global R&D pipeline, specialty products will continue to drive growth in the market (see Exhibit 4). For example, a new wave of treatments for hepatitis C offers the promise of halting disease progression, preventing the occurrence of end-stage renal disease and liver cancer.

Exhibit 4: Global New Molecular Entities Launched and New Brand Spending Growth



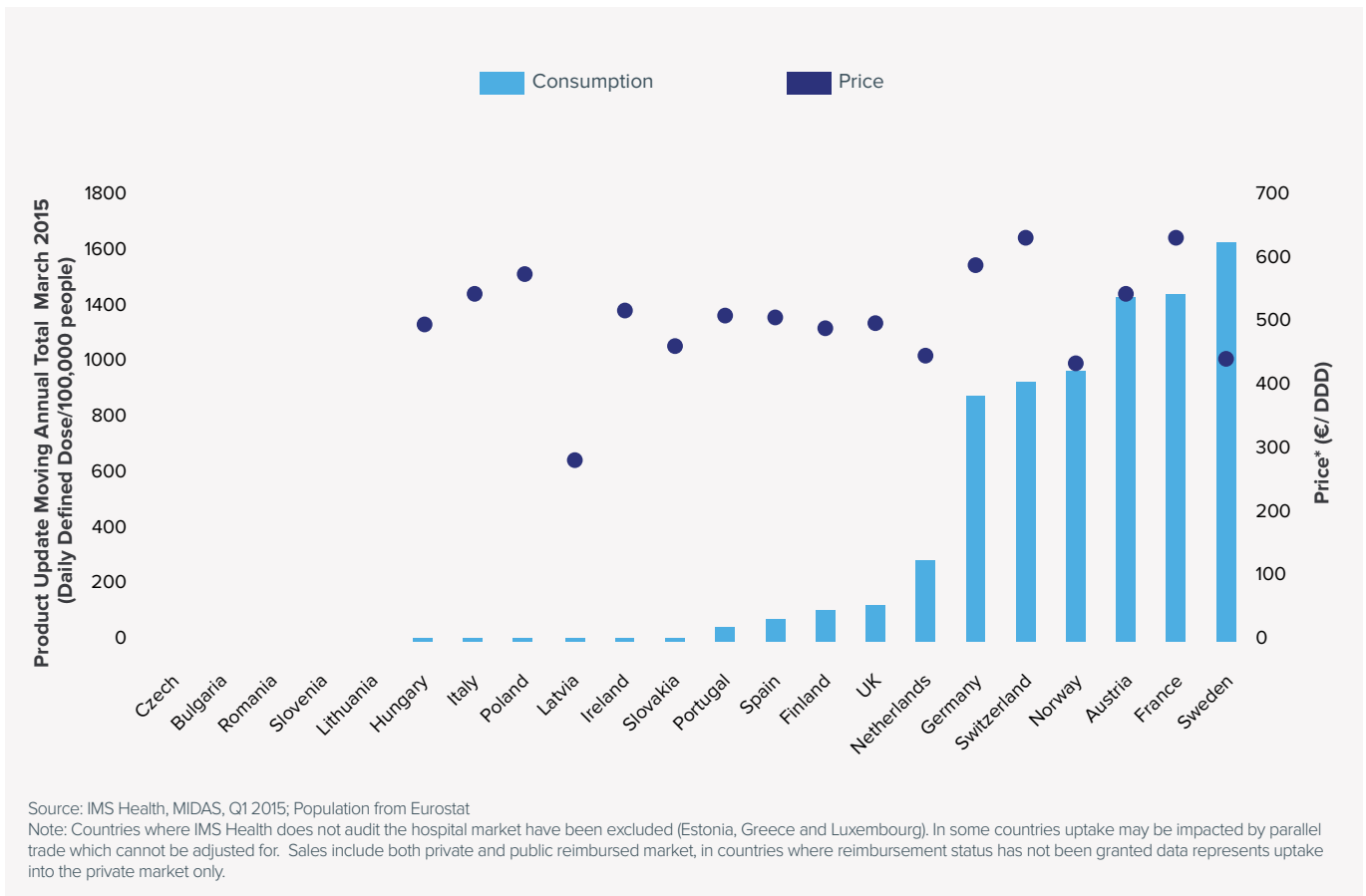
A breakthrough medicine from Gilead, sofosbuvir (Sovaldi), cures hepatitis C in more than 90% of patients in just 12 weeks. Prior to the availability of Sovaldi and other recently approved medicines, the cure rate for hepatitis C using interferon-ribavirin was no better than 50%. The therapy caused serious side effects — including nausea, diarrhoea, itchy skin rashes, insomnia, and severe depression—preventing many patients from completing the full course of treatment.

THE NATURE OF THE CHALLENGE

Such innovations, however, often come at a high price. In France, the cost of Solvaldi when launched was €52,500 per patient, and in Q1 2015, the medicine accounted for 1.4% of the country’s total pharmaceutical spend, versus 0.8% a year earlier. In Sweden, Solvaldi accounted for 3.2% of the pharmaceutical spend for the country in Q1 2015, versus 0.2% the year before. The uptake and price of Solvaldi varies widely across EU countries as illustrated in Exhibit 5.

Such examples of breakthrough therapies illustrate the challenge facing healthcare providers in affording access to these new medicines without disturbing the status quo in other therapeutic categories.

Exhibit 5: Solvaldi Uptake and Price, by Country

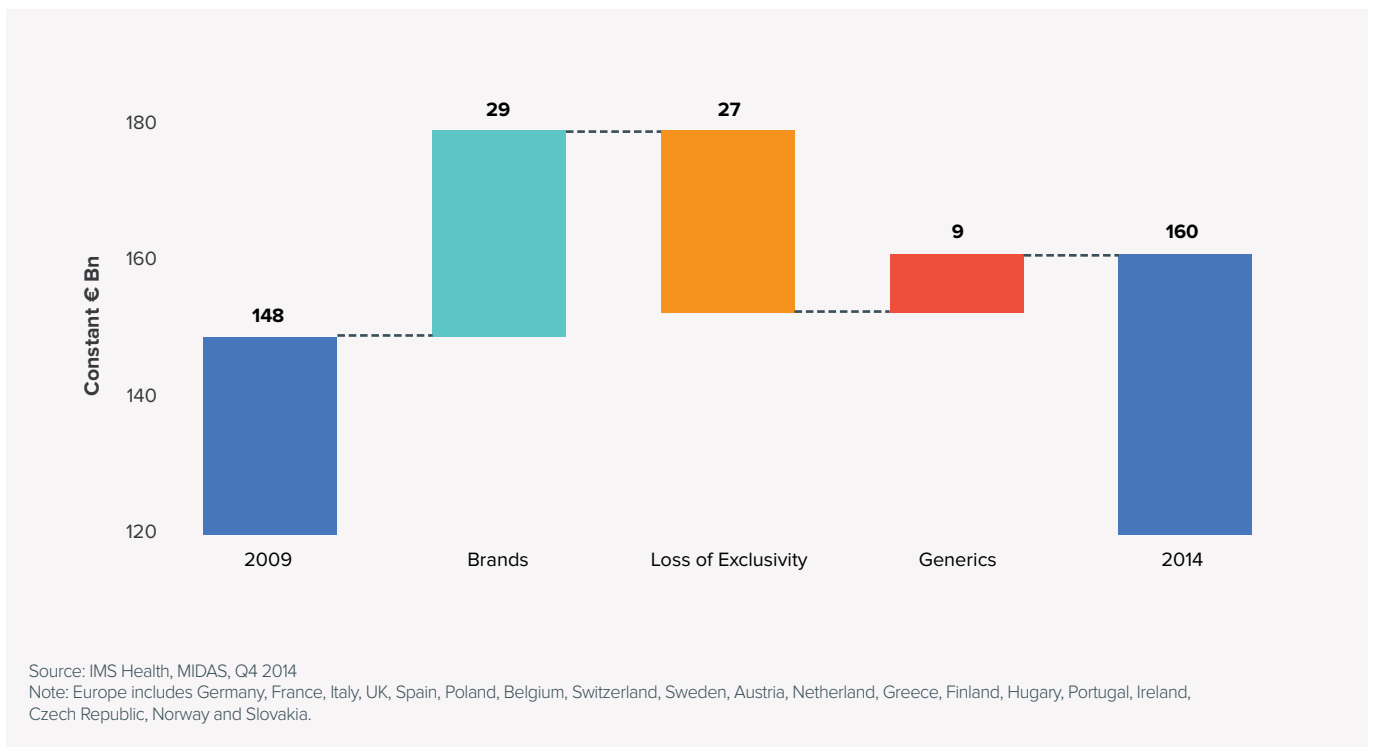




#### 4. The savings potential from patent expirations will decline over the next few years

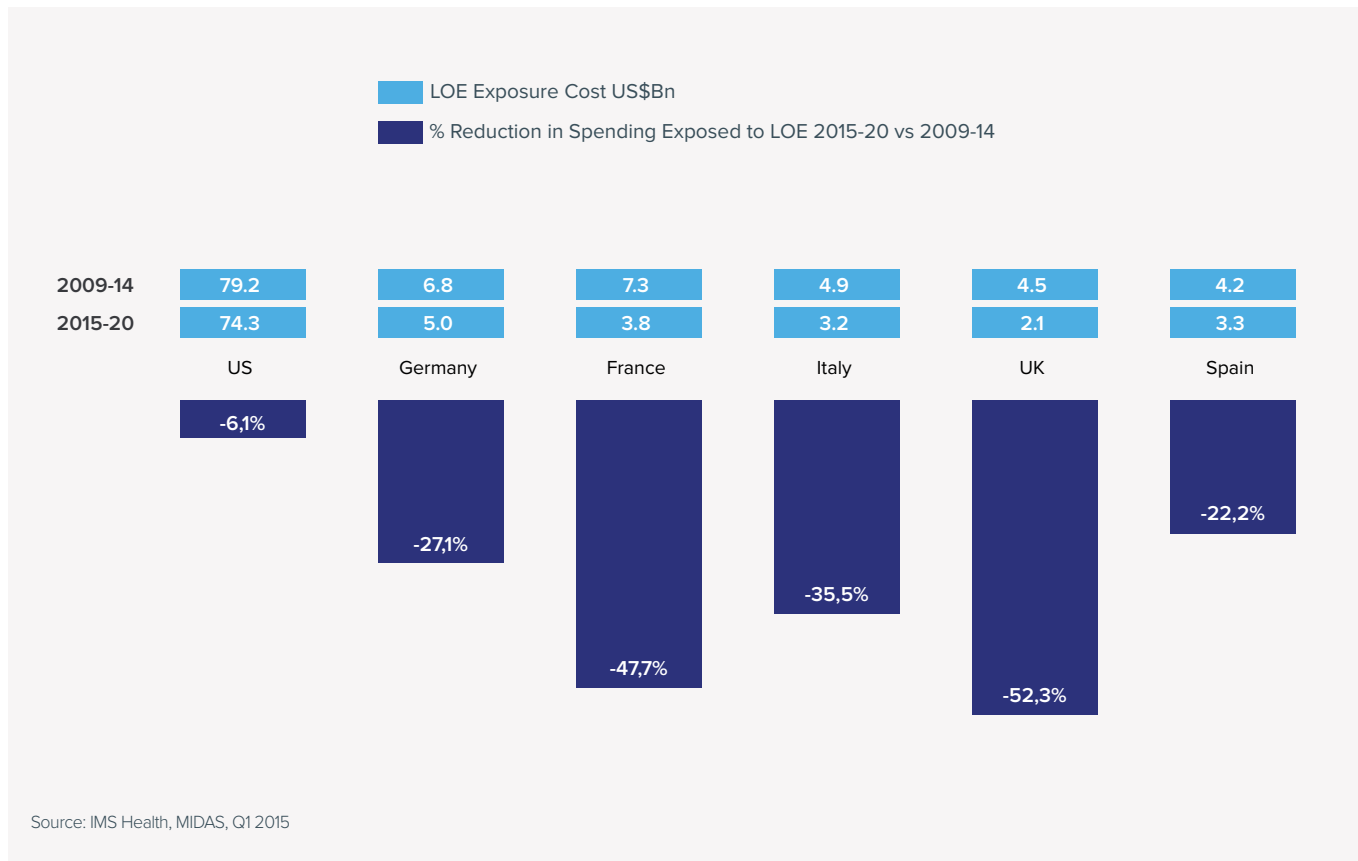
Over the past 5 years, the availability of generic medicines has contributed to cost containment in overall spending growth. Within the EU, the availability of generic medicines and effect of patent expiries has helped to offset the increase from branded medicines growth (see Exhibit 6).

Exhibit 6: Components of Change in Total Medicines Spending in Europe



Following several years of opportunity for savings in medicine spending fuelled by the expiration of numerous blockbuster medications (with a peak in 2012), there will be fewer such opportunities through 2018. In 2014, health systems in Europe were able to save €100 billion due to patent expiration, while in the next five years, the potential savings will be markedly less. Savings from patent expiry vary by country, but overall in the next five years, there will be between 20-50% less opportunity than in the previous five years (see Exhibit 7).

Exhibit 7: Patent Expirations 2009-2020



# Quantifying the Recent Contributions of Generic Medicines

## 1. The entrance of generic medicines drives down the price of off-patent products by 61%

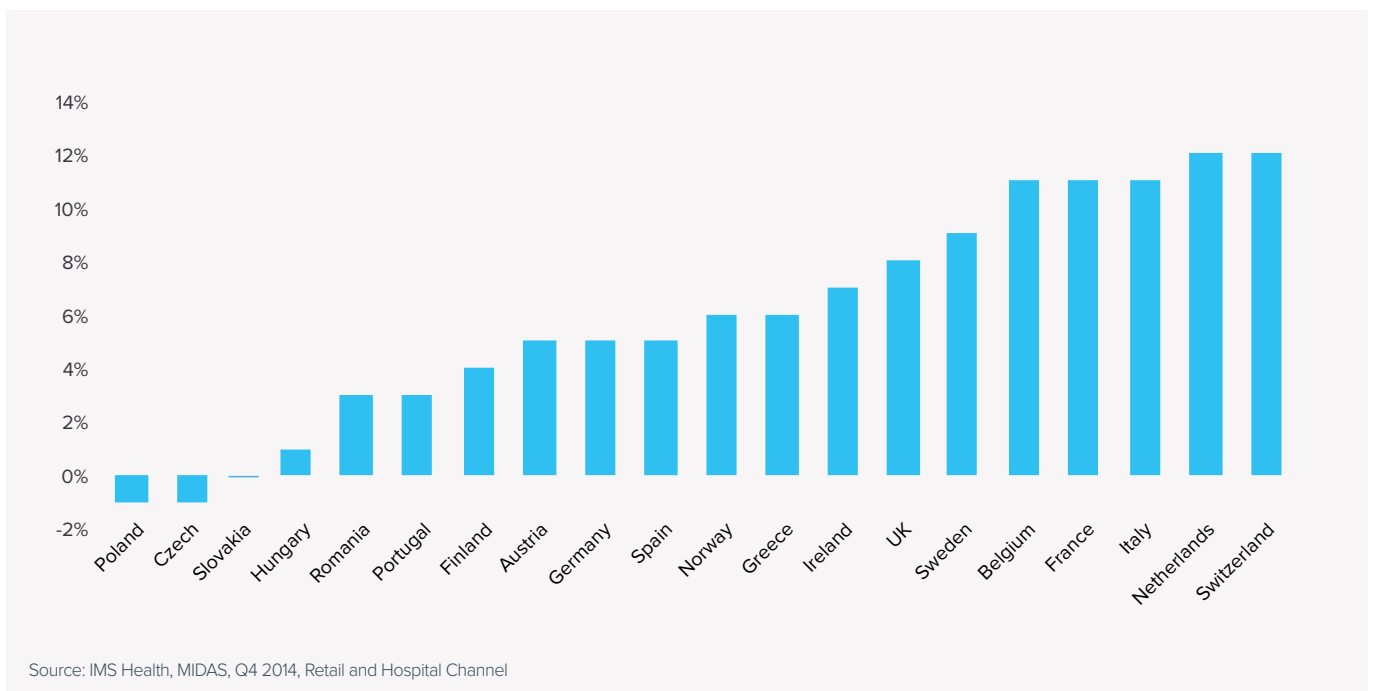
The vast majority of all pharmaceutical treatment in the EU is performed with established products/ molecules that have lost patent/exclusivity (off-patent products). These can be either off-patent originator medicines or generic medicines. While generic medicines are produced to the same quality standards as the originator and approved according to a special regulatory process, their prices are 61%<sup>5</sup> lower than those of the originator product prior to patent loss.

The prescriber's decision to use an off-patent molecule may be impacted by many factors. Cost containment is just one aspect and may be problematic, particularly if prescribers do not have visibility to cost or they do not view it as an important consideration. When cost is not the determining factor, prescribing decisions are influenced by:

- The need to continue a patient's existing medication
- A lack of knowledge and understanding of off-patent products
- Formulary guidelines
- A lack of experience with newer products

In 2014, all off-patent medicines (off-patent brands and generics, combined) accounted for 92% of all prescription volume (in standard units) and only 47% of the value. This is a major shift since 2005 when the off-patent market represented 83% of volume and 42% of value. The change in off-patent volume market share over the last five years varies greatly across countries, as seen in Exhibit 8.

Exhibit 8: Off-Patent Market Share Change 2009-2014



Across the region, the share of never protected off-patent medicines (including generics, never protected brands and branded generics) accounts for 27% of the total pharmaceutical market in value and 68% in volume, although the share varies by country, as is visible in Exhibit 9.

Savings from the off-patent sector also vary by country, as is clear in Exhibit 10.

For example, in the U.K., total pharmaceutical spending was reduced by 70% after the entrance of generic medicines. An additional 9.8% savings could be achieved if generic medicines reached 100% penetration. In contrast, in Spain, only 52% savings were achieved; however no new savings can be generated due to the fact that prices of off-patent originals now match the price of generic medicines.

Despite the lower cost of generic medicines, price savings are achieved mainly where competition is encouraged—meaning that pricing structures are not regulated. (Indeed, the free-market pricing system in the U.S. appears to yield the highest off-patent efficiency of any market.) In most EU markets, the price of the off-patent product is commonly lowered significantly, either through competition from the generic version or because authorities force a price reduction. In addition, the entry of generic medicines may also precipitate enforcement of a price reduction on originator brands in some countries. This generates significant savings, even though the generic medicine share may actually be low.

According to our calculation, the entrance of generic medicines drives down the price of off-patent products by 61%<sup>5</sup>. This measure of off-patent efficiency is based on the difference between the current price of each off-patent product and its average price over the year prior to patent expiry. On this basis, spending on medicines in 2014 was €100Bn less than it would have been if prices had not been lowered with the introduction of generics.

Exhibit 9: Protected and Off-Patent Market Share by Country, 2014

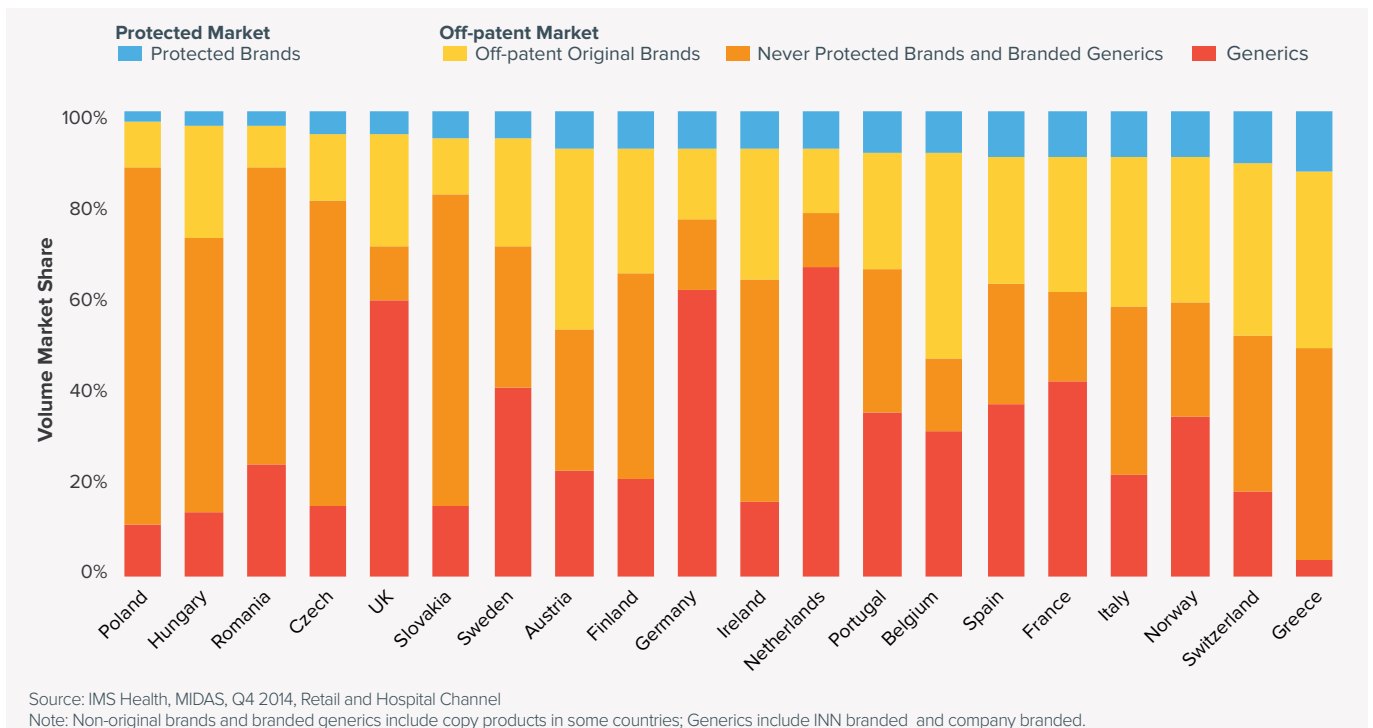
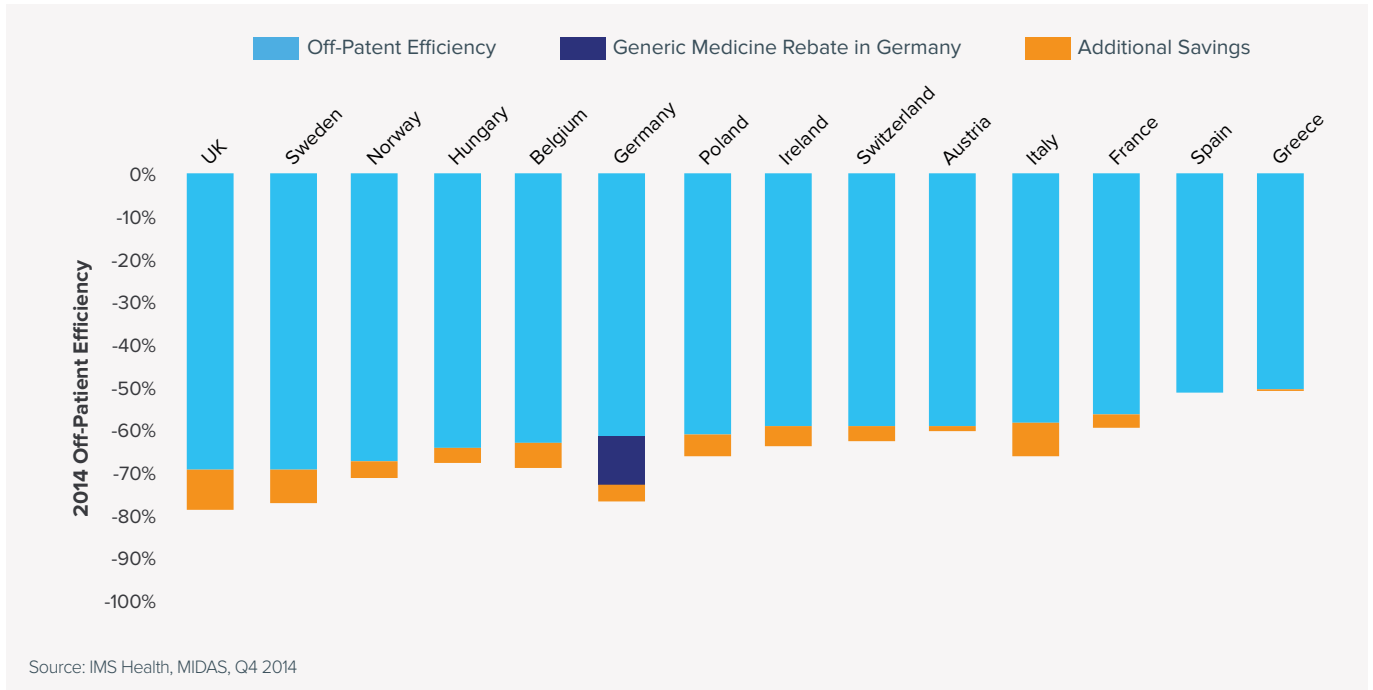
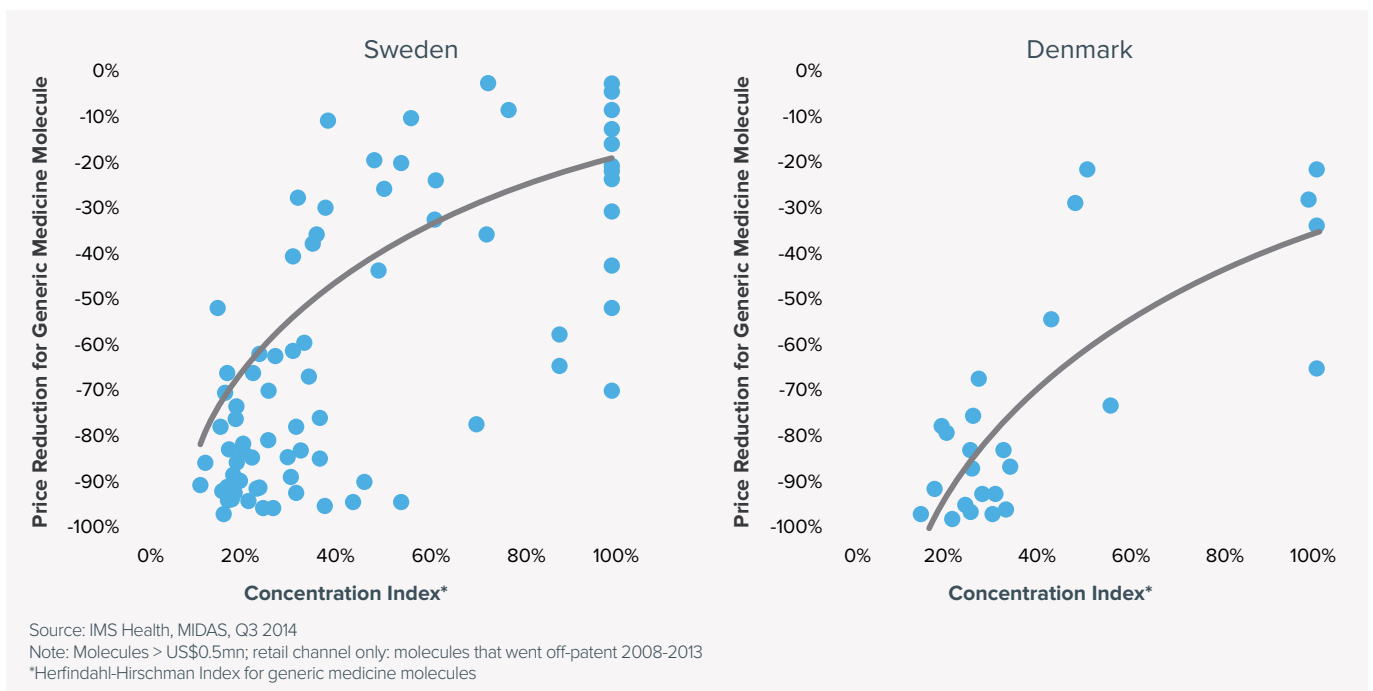


Exhibit 10: Savings from Generic Medicine Competition by Country



The issue of competition is complex. The lowest prices are most visible in tender-like markets. Exhibit 11 plots market concentration against price for two countries that have tendering systems for generic medicines: Sweden and Denmark.

Exhibit 11: Generic Medicine Molecules Concentration Index vs. Price Reduction<sup>6</sup>



QUANTIFYING THE RECENT CONTRIBUTIONS OF GENERIC MEDICINES

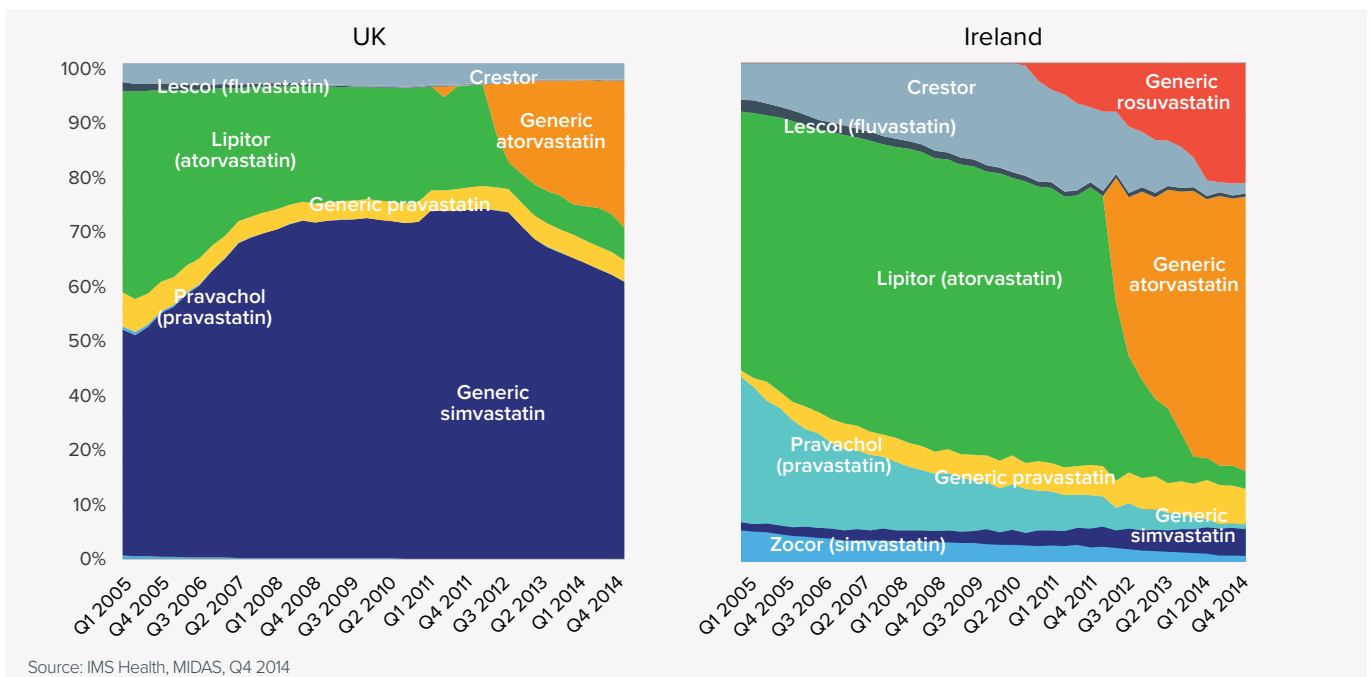
Both countries show very high savings for molecules with a low concentration index (in other words, a very high level of competition, typically with several companies all having a relevant market share). Where there is less competition, prices are higher. In the Swedish case, several competitors with similar shares are needed to achieve high savings.

Countries in which the price of generic medicines is regulated also experience similar price competition. In most cases, pharmacies benefit from such competition in the form of discounts. In many markets, the discounts are an important part of pharmacies’ earnings, and the discounts reduce the pressure to increase dispensing fees.

Competition does not, however, revolve around price, exclusively. Exhibit 12 shows the market share of statins over time in the United Kingdom and Ireland. In both countries, when generic medicines become available, the generic version eventually, over a period of time, takes the major share of the molecule. However, the choice of molecule can play out two different ways when some products in the class are still patent protected. In Ireland, the promoted, still patent-protected product increases share versus the off-patent molecules; doctors are receptive to the innovator’s promotional messaging. In the U.K., physicians appear less receptive to the promotional messages, and the use of prescribing guidelines and formularies drive the use of lower-cost alternatives.

The implication in markets such as Ireland is that generic medicines, too, need to be promoted if they are to maintain or gain share, which would increase the cost of generic medicines significantly. The implication for a market such as the U.K. is that new innovative products have greater difficulty in garnering a premium price over the off-patent molecule.

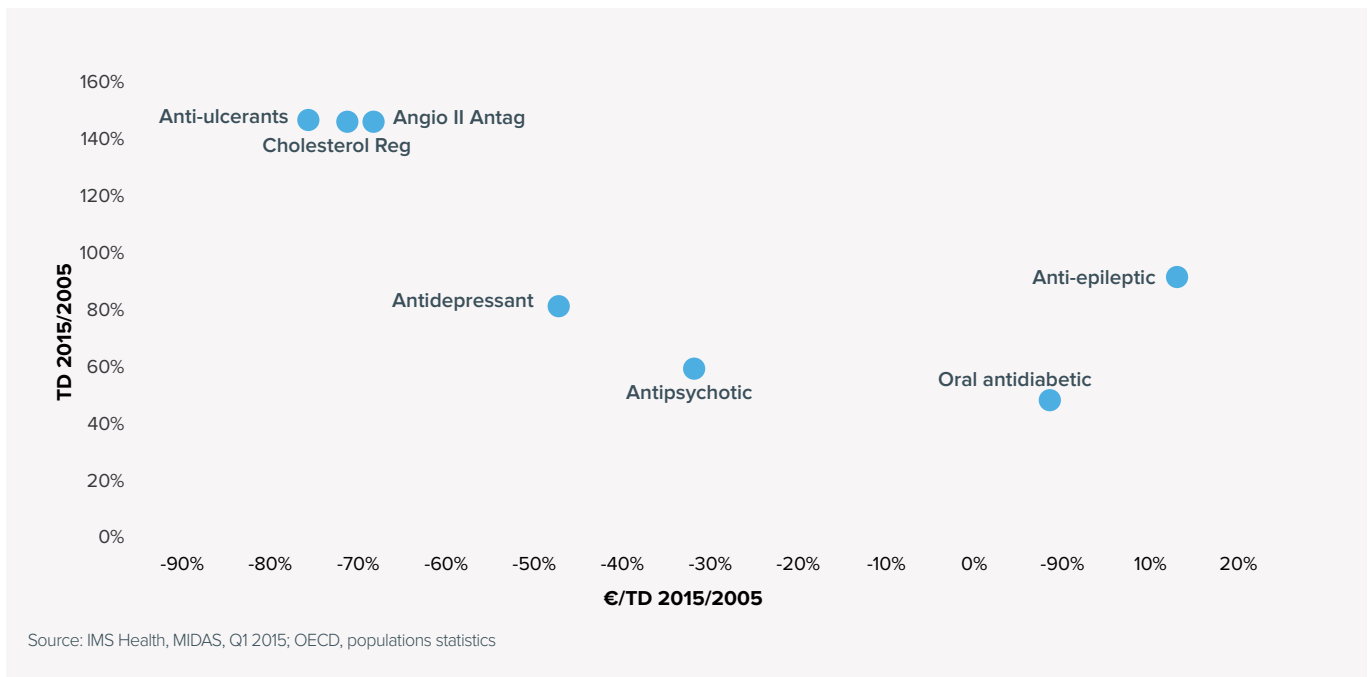
Exhibit 12: Volume Dynamics of the Statin Market, UK and Ireland



**2. In chronic disease areas, patient access to treatment has doubled, while spending remains flat**

Patient use of medicines is driven by disease prevalence, treatment guidelines, availability and affordability. There can be little doubt that given their affordability, generic medicines have increased patient access to and use of medicines. To gain a detailed picture of the impact of patent expirations on both cost and access, key therapeutic areas were studied in all European countries over 10 years, analysing the mix of products, volumes, and prices. In the seven therapeutic areas studied, prescription volumes continued to grow as prices decreased and resulted in lower cost per treatment day (see Exhibit 13).

**Exhibit 13: Price Reduction and Number of Treatment Days**



The use of anti-epileptic medicines serves to illustrate that in some therapeutic categories, there is a perceived need to prescribe the originator product, despite the availability of lower cost generic medicines.

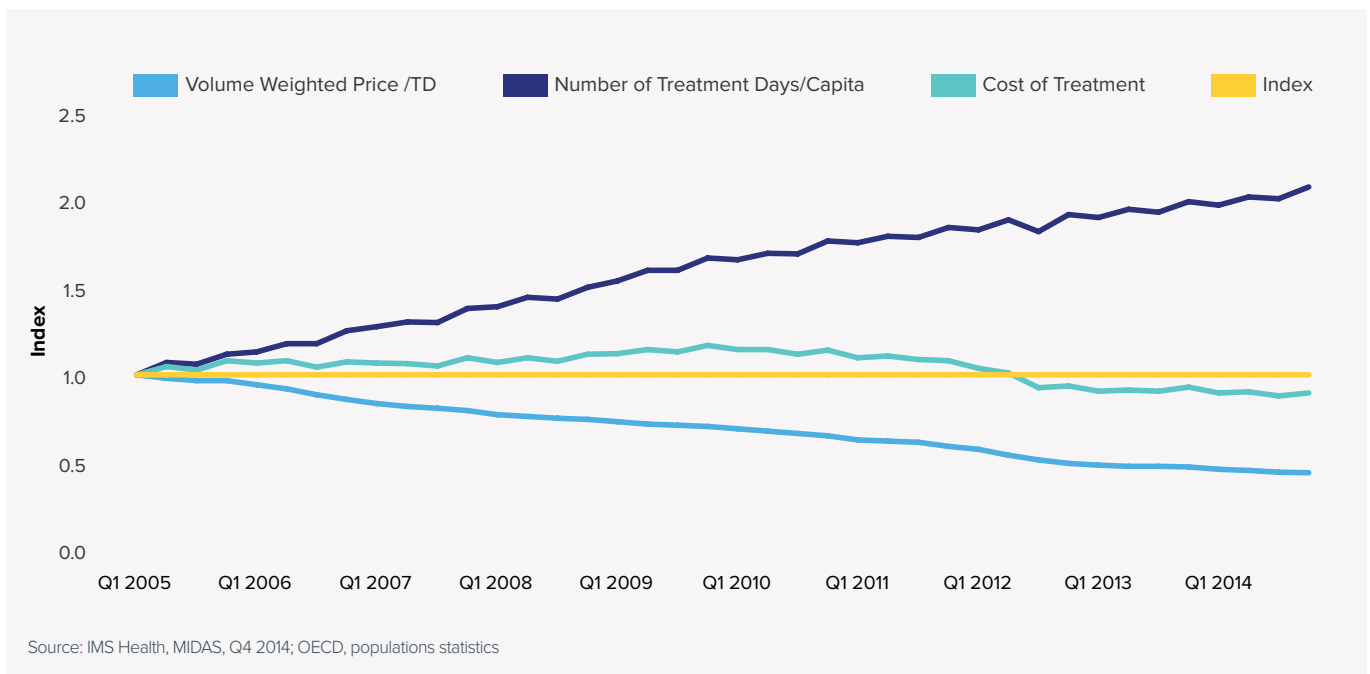
## QUANTIFYING THE RECENT CONTRIBUTIONS OF GENERIC MEDICINES

As seen in Exhibit 14, the overall, 10 year trend in the EU across seven therapeutic areas<sup>2</sup> has been:

- A drop of >50% in the price of medication per treatment day
- An increase of >100% in prescription volumes (in part because a lower cost has increased access)
- Flat total spending that is on par with what it was 10 years ago, although lower than 5 years ago

It should be noted, though, that increased utilisation is not all due to greater affordability. Other reasons include changes in the population's health and modifications in clinical guidelines.

### Exhibit 14: Evolution of Volume, Price, and Treatment Cost in Seven Therapy Areas





## Different Approaches to Off-Patent Product Pricing

Inherent political differences across EU Member States give rise to highly variable pricing systems for off-patent medicines, of which there are three main types:

- Most commonly, European markets regulate the reimbursed price for off-patent medicines relative to the price of the original brand prior to patent expiration. For example:
  - In France, generics must be priced at least 60% below the manufacturer's selling price of the branded original, prior to patent expiration. Notably, the price of the off-patent original is cut by 20% upon commercialisation of the first generic medicines version. Subsequently, the prices of the off-patent original and their generic medicines versions are cut 18 months after the patent expiry of the branded original, unless they have been incorporated into the reference price system in the interim.
  - In Norway, The Norwegian Medicines Agency establishes maximum pharmacy purchase prices (PPP) for all generic medicines in the same way as for all other prescription medications. For active ingredients impacted by the stepped-price system (Trinn pris systemet), the price of generics cannot exceed the maximum PPP of the corresponding original brand. If the active ingredient is not subject to the stepped-price system, generics prices are set at the lowest available maximum PPP for the active ingredient.
- The reimbursement price can also be set based on tendering-like system.
  - In five EU countries (Germany, the Netherlands, Sweden, Denmark, and Hungary), the retail price of a generic medicine is based on a tender-like model and is set by the lowest bid. Bidding the lowest price will either provide the bidder with volume exclusivity or will establish the reference price. In all cases, the healthcare system will reimburse at the lowest price.
- The reimbursement amount is set based on market prices.
  - In the U.K., prices are set by the market; there are no fixed prices established either for the payer or the patient. The National Health Services' list price for an unbranded generic medicine cannot exceed the list price of the off-patent original.

When pricing in the off-patent sector is not regulated, it is influenced by several other factors such as molecule sales, form, age since patent expiration, and, ultimately, the level of competition.

### 3. Benefits accrue in different ways across countries

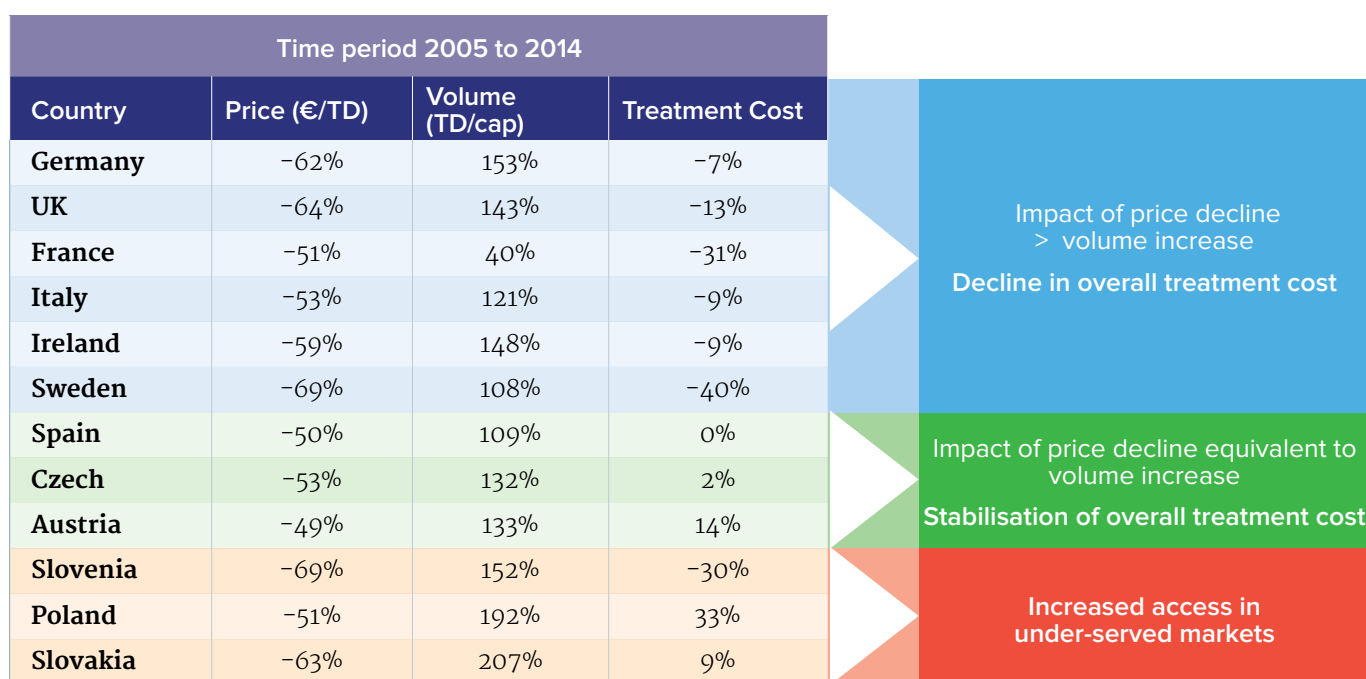
This increased access to affordable medicines delivers long-term benefits to society and to healthcare providers. However, the specific trends are not uniform across all European countries, as shown in Exhibit 15.

While considerable price reductions are seen in many countries, the treatment cost (as measured by Defined Daily Dose (DDD)) in the same seven therapeutic areas still varies greatly between countries (see Exhibit 16).

The high increased access in countries such as the United Kingdom, Denmark, and Germany stems largely from an early use of medicine to prevent problems. An example is the extensive use of cholesterol-lowering medicines to reduce cardiovascular risk (see Exhibit 17).

Antidepressant usage shows a much more dispersed pattern (see Exhibit 18). Individual countries have different attitudes toward depression, leading to differing diagnosis levels and approaches to treatment. Where countries may be underutilizing medicine, the impact of affordability is far less apparent.

**Exhibit 15: Comparison of Changes in Price, Volume, and Treatment Cost across Seven Therapy Areas by Country**



Source: IMS Health, MIDAS, Q4 2014; OECD, population statistics

Exhibit 16: Cost per Treatment Day in Seven Therapeutic Areas, 2014

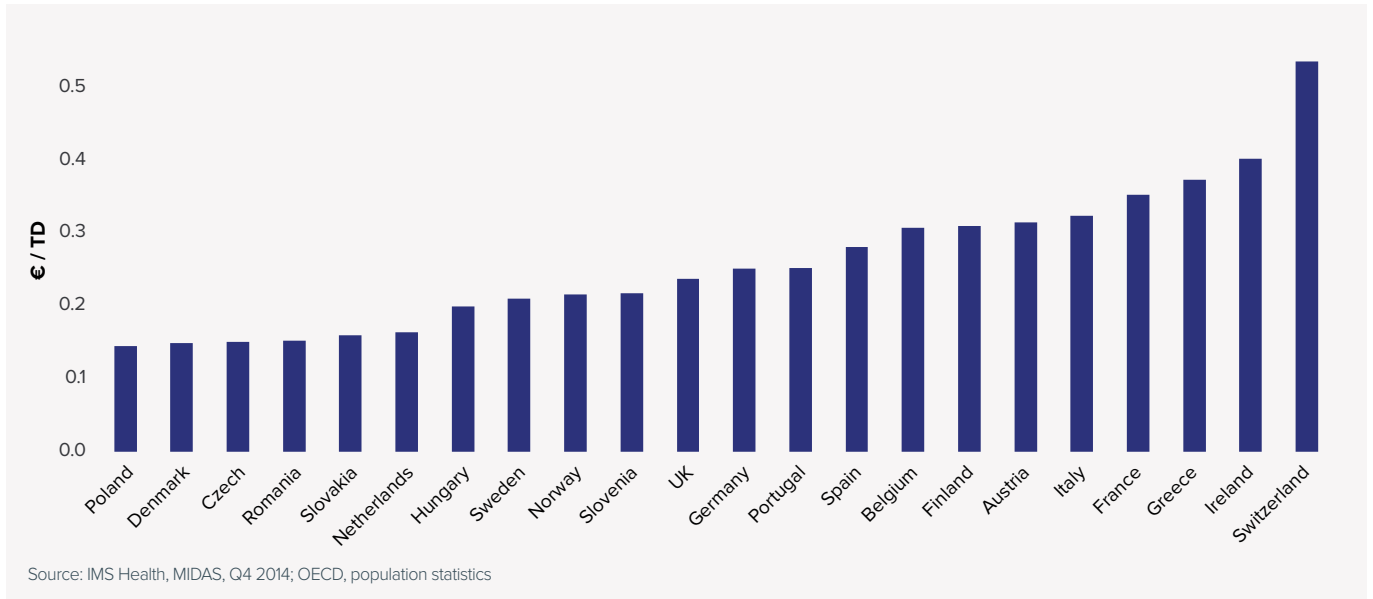


Exhibit 17: Treatment Days, per Capita in Cholesterol Regulators across Countries, Q4 2014

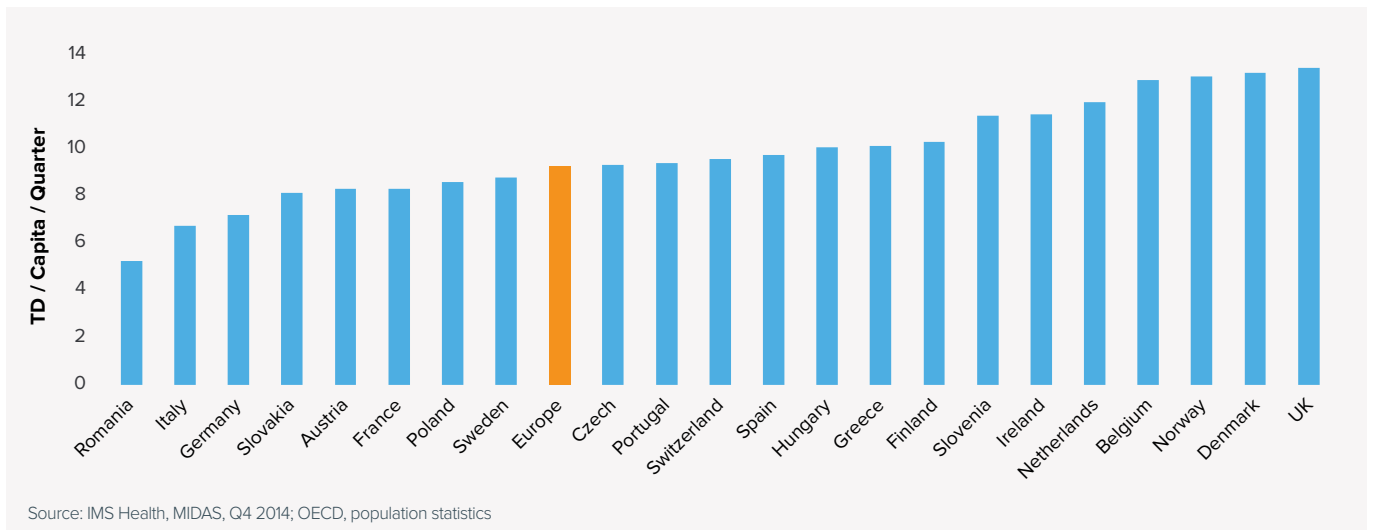
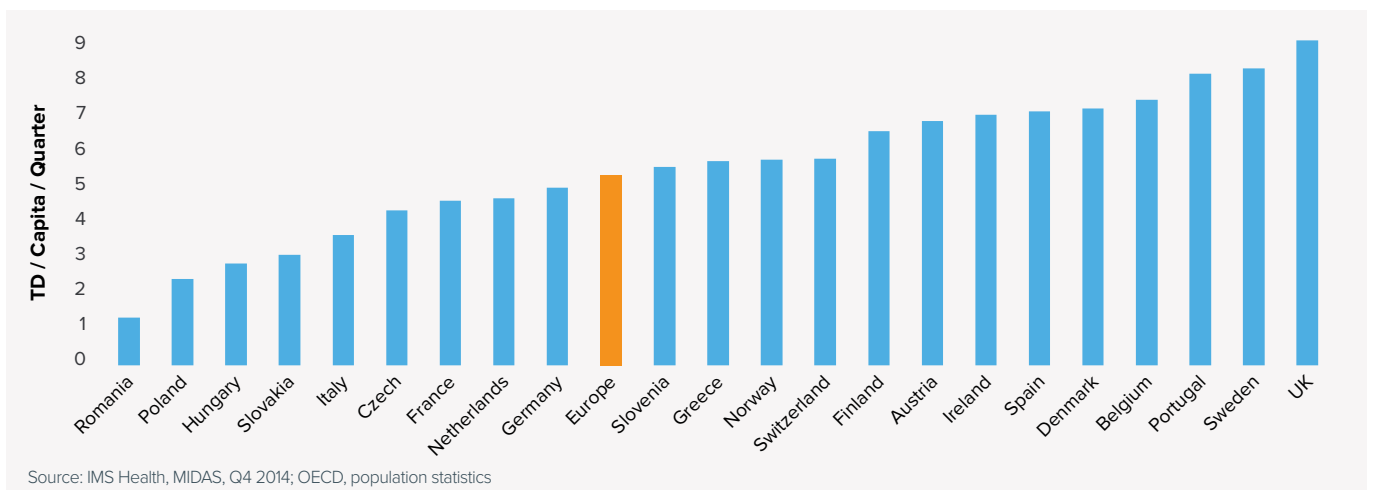


Exhibit 18: Treatment Days, per Capita in Antidepressants across Countries, Q4 2014



# Maintaining the Contribution of Generic Medicines: The Way Forward

As countries look ahead to the consequences of ageing populations, increased chronic disease, and a surge in innovative treatment options, maintaining the contribution that generic medicines can make to sustainable health systems is essential. A number of observations are presented here in the interests of advancing understanding of ways in which stakeholders can appropriately support the role of generic medicines.

## 1. Cost savings should not be the only criteria in evaluating generic medicines

When evaluating the benefit of lower priced medicines, one must take into consideration the following factors:

- **Industrial policy**

The pharmaceutical industry is an important sector in the EU economy as well as in individual countries. In countries where the net export of patented medicines is high (as Switzerland, Ireland, Denmark, Sweden), the government tends to support the industry by allowing relatively higher prices on patented medicines. Similarly, countries with a local generic medicine industry (such as Hungary) frequently want to support local manufacturing by allowing a price that sustains the generic medicines industry.

Currently, 75% of the generic medicines consumed in Europe are produced in Europe. Within tender markets, there is a higher share of generic medicines produced outside of Europe, which pushes away companies that are not able to compete on price. In order to compete, European firms often contract with Indian manufacturers for production.

- **Risk of shortages**

Because producing lower-priced medicines is less financially attractive for manufacturers, they may elect to withdraw from certain markets, resulting in medicine supply disruptions or shortages. And, when volumes are also low, manufacturers may discontinue products or formulations altogether. The Foundation for Pharmaceutical Statistics in the Netherlands reports that 3-4% of the products that have won the tender are not available to the pharmacy when they are to be dispensed. This led to an additional cost of around €60M/year due to additional labour costs for dealing with these shortages.<sup>7</sup>

- **Indirect impact on the supply chain (wholesalers and pharmacies)**

A country's policies on off-patent pricing have the potential to impact wholesalers and pharmacies in several ways. First, it may be necessary to stock multiple products (of the same form and strength) for a given molecule, making it difficult to forecast the right product mix. If substitution is not freely allowed as it is in tender-like systems, supply will not always match demand. Second, the remuneration structure for wholesalers and pharmacies is often linked to pack value, with the result that companies along the supply chain suffer financially when prices are lower. A better remuneration model for wholesalers and pharmacies is one that bases their remuneration primarily on the number of packs (as in Germany) and services provided.

- **Trust from patients, prescribers, and pharmacists**

Pharmaceuticals are unique products in the degree to which patient trust matters. Trust in the brand or the manufacturer can affect both adherence to the treatment regimen and subjective views on therapeutic outcomes (via the placebo effect). The trust of all health professionals is also key to the uptake of generic medicines. Prescribers and pharmacists should collaborate in playing an active role in building and maintaining trust in generic medicines.

## 2. The environment must be conducive to generic medicines utilisation

To maximize the contribution of generic medicines to the affordability and sustainability of the healthcare system, the generic medicines industry must be able to operate within a sustainable, competitive, and efficient market model. Certain conditions in the broader pharmaceutical market must be met to create an environment conducive to allowing generic medicines to have the desired impact. These include:

- **Sufficient competition**

Maximum price reduction can only be achieved when effective competition exists between generic medicines and off-patent original brands. The number of competitors for a given product has a greater influence on prices than do regulated price reductions, due to the above-mentioned discounts used to support the supply chain. In France and Spain, where the price of off-patent original brands tends to be low—and in many cases equal to—generic medicine prices, additional competition is generated.

- **Reliability and continuity of supply**

Generic medicine manufacturers depend on having high-volume markets where their goods are sold at an acceptable ex-factory price. Markets with low usage volumes of low-cost generic medicines may find it difficult to source some generic medicines in the future and may experience product shortages.

- **A recognition of the value of generic medicines**

Generic medicines, having undergone strict scrutiny before being licensed and given market approval by the European or national medicines authorities, provide the same quality, safety, and efficacy as the original brand name product. In addition, the availability of lower-priced generic medicines brings down the price of originator medicines through market competition, producing even further savings to healthcare system and ensuring access for patients.

## 3. Effective use of generic medicines depends on multiple stakeholders

A sustainable healthcare system is dependent on how viable the different stakeholders in the system remain, as outlined below:

### **Originator manufacturers**

- It is essential that the research-based pharmaceutical industry remains focused on the discovery and development of innovative medicines and brings products with true benefit to the market. .
- Investment in new treatments needs to be rewarded with acceptable pricing and usage.

For countries to afford new treatments, they must realize savings after patent expiration through a combination of approaches, including generic medicine competition.

### **Generic medicine manufacturers**

- The system must be structured to reward investments that add competition and incremental improvements with fair pricing and sufficient market share.
- A major requirement is a level playing field with a predictable approach to pricing, transparent procurement policies, and an efficient regulatory approval system. Access decisions need to be made not based on price alone, but also considering reliability of supply, product quality, and the overall economic value to Europe.

### **Wholesalers**

- The remuneration system needs to be aligned to the market structure and the changing price structure of goods.

### **Prescribers**

- Prescribers must be educated in the need for generic medicines and be able to communicate this effectively to patients when a generic medicine is prescribed.
- Prescribers should be placed at the heart of a strategy for the uptake of generic medicines.
- Prescribers must be familiar with the availability of off-patent molecules.
- They must also be aware of cost considerations to the patient and therapeutic alternatives.

### **Pharmacies**

- Pharmacists must be educated in the need for generic medicines and be able to communicate this effectively to patients when a generic medicine is dispensed.
- Care should be taken so that introducing multiple potential vendors for a product does not unduly increase pharmacies' workload and costs.
- Remuneration systems need to be adjusted to accommodate large volumes of very low cost products. (If the price of generic medicines is very low, the incentive for pharmacists to dispense them is minimal, since part of their remuneration is frequently based on the value of each item dispensed.)
- Pharmacists should not be disincentivised from driving savings from lower cost, multi-sourced generic medicines.

### **Patients**

- Patients should be informed about the differences / similarities between available brands and generic medicines and have a clear understanding of the product information.
- Patients who are willing to pay the extra cost should have the option to purchase a premium-priced brand.

### 4. Policymakers must actively pursue a social agenda that recognizes the full role of generic medicines

Generic medicines, through their lower costs and the competition they create, help to deliver savings that are vital to the development of a more sustainable healthcare system. However, for this sector of the industry to be an effective resource in ensuring broad access to medicines over the long term, the following steps will need to be taken:

1. Multiple stakeholders must come to a consensus on the role of generic medicines, creating explicit measures of their success and identifying specific elements that require further study and discussion. Biosimilars will undoubtedly play an important role in the market's future dynamics; however biosimilars are beyond the scope of this paper and have, therefore, not been addressed.
2. Pricing mechanisms must be structured to encourage competitive entrants and benefit payers.
3. Key stakeholders—prescribers, pharmacists, and patients—all need to be aware of the benefits of generic medicines and be incentivised to use them.
4. Rules must be implemented that allow for substitution with generic medicines either by International Non-proprietary Name (INN) prescribing or by the pharmacist having the right to substitute.
5. Patients need to retain the right to exercise a preference for a branded product, albeit at an additional out of pocket cost.
6. Measures should be focused on ensuring the stability of supplies. Tendering tends to increase the risk for supply swings, which increases cost in the overall system and the risk for shortages.
7. The European industrial agenda should include a focus on generic medicine manufacturing. The opportunity exists for governments and payers to incentivise the European generics medicine sector in order to support continued cost savings through gold standard therapies at affordable prices. Europe needs to support its generic medicine industry if it is to retain development and manufacturing bases. Consolidation will continue, and if Europe is not an attractive place for investment, then any overseas acquirer will seek to move its operations elsewhere.

## Conclusions

The off-patent medicines industry is an essential and integral part of healthcare delivery across Europe, supplying over 90% of the volume demand for medicines, while contributing just 47% of the cost. In 2014, generic medicines reduced the region's medicine bill by 61%, both through directly offering products at lower prices and by introducing competition that drives down the cost of originator brands that are off-patent. In the seven chronic disease areas analysed, this has had the general effect of doubling patients' access to treatment, while holding costs steady. Although these benefits accrue differently across EU member countries, the implication is clear: the generic medicines industry has been vital to sustaining healthcare benefits in the region.

Without the savings from the off-patent sector, governments and payers could likely not have met the growing demand for medicines over the past 10 years. And, given the region's ageing population and the introduction of costly breakthrough medications, realizing savings of this magnitude will be necessary well into the future. Depending on market factors, some potential remains for existing off-patent molecules to drive further savings including via switches from original to generic medicines. In the coming 10 years, there are some additional savings to be had from small molecule patent expiries, but the largest opportunity will come from the use of biosimilars, which this document has not covered.

Still, cost savings is not the only factor that should be considered when evaluating the impact of generic medicines on the broader healthcare system. There are potential offsets to this benefit, including the risk of medicine shortages, the impact on industrial policy and the supply chain, and issues of stakeholder trust.

The continued health and level of contribution of the generics medicine industry is not a foregone conclusion. For healthcare systems to be sustained, the generic medicines industry itself must be sustained. This will require maintaining an environment that is conducive to an increasing use of generic medicines through a proactive social agenda and enlisting the support of multiple stakeholders.



## Terms of Use

Throughout this report, we have classified products according to their patent status—with very specific meanings for the following terms:

**Patent Protected Products:** Original products that, by law, have marketing exclusivity for some period of time following introduction in the market. Example: Solvaldi.

**Off-Patent Products:** Products on which there are no exclusive marketing rights. These can either be branded products whose patent has expired, or generic medicines.

**Off-Patent Brands:** Products on which the patent has expired, but that are still marketed by the originator company, under the same brand name. Example: Lipitor.

**Generic Medicines:** Products introduced after the original's patent has expired, which have the same "qualitative and quantitative composition in active substance and the same pharmaceutical form as the reference product, and whose bioequivalence has been demonstrated."<sup>8</sup> Example: atorvastatin.

## References

1. ([http://ec.europa.eu/health/reports/docs/health\\_glance\\_2014\\_en.pdf](http://ec.europa.eu/health/reports/docs/health_glance_2014_en.pdf))
2. Seven therapeutic areas include angiotensin II antagonists, anti-epileptics, antipsychotics, anti-ulcerants, cholesterol regulators and oral antidiabetics. These therapeutic areas are selected based on broad usage and consistent treatment pattern and mix of generics and brands across European markets.
3. IMS Institute report: *Bringing Healthy Living to Ageing Citizens: the Role of Technology*, June 2014.
4. ([http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0008/96632/E93736.pdf](http://www.euro.who.int/__data/assets/pdf_file/0008/96632/E93736.pdf))
5. Off-patent efficiency is calculated for all off-patent products and is based on the difference between current price of the off-patent product and average price in the last 10 years before patent expiry. 61% is weighted average for 14 EU markets which represent 91% of total EU market in values.
6. Herfindahl-Hirschman Index (HHI) is a commonly accepted measure of market concentration and determines if the industry is competitive or nearing monopoly. The closer a market is to being a monopoly, the higher the market's concentration (and the lower its competition).
7. Levering preferente middelen blijft probleem, 13 september 2012, *Pharmaceutisch Weekblad*, Jaargang 147 Nr 37
8. Generics and Biosimilars Initiative, *Official Journal of the Generics and Biosimilars Initiative*, 2015.

# About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care. With access to IMS Health's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS Health information and expertise to support the advancement of evidence-based healthcare around the world.

## Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

## Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

# IMS INSTITUTE

FOR

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