

COMMUNICATIONS TOOLKIT

Generic Medicines Group

November 2016

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1. Generic Medicines today

The generic medicines industry is at the heart of public health delivery. This industry provides essential medicines that European patients, healthcare professionals and healthcare systems rely on to treat most acute and chronic ailments ranging from cardiovascular, to diabetes and even to cancer. Generic medicines have transformed healthcare in Europe by significantly increasing access to medicine for patients in an era of rising demands for healthcare services and constrained finances. Over the last ten years, **generic medicines have increased access to medicines by over 100% in 7 key therapeutic areas** without increasing the overall treatment cost. Millions of European patients have benefited from better access to gold standard therapies as a result of this transformation.

Generic medicines are for Patients

Generic medicines create better value for health at many different levels:

- increasing access to medicines for all patients across therapeutic areas;
- improving health outcomes by improving cost-effectiveness of existing therapy and ensuring more and, where medically relevant, earlier access to gold standard therapies for patients;
- reducing health inequalities by enabling access to patients in previously underserved markets in Europe;
- improving medication adherence by reducing the financial burden (i.e. co-payment) for patients purchasing medicines.

Generic medicines stand for Quality

Generic medicines are subject to stringent EU and national regulations governing their approval, quality, manufacturing (GMP) and post-marketing surveillance (pharmacovigilance) to ensure the highest levels of safety, quality and efficacy. Our industry is both committed to fulfilling these requirements and is also in regular dialogue with European and national regulators to maintain high standards for Europe and to promote these standards globally.

Generic medicines are about more Value

Generic medicines create economic value in three major areas: by considerably increasing the supply of medicines (a more competitive market), by supporting sustainability of healthcare budgets (reducing pressure on public and private healthcare budgets) and by generating new employment, manufacturing and investment opportunities (a positive macroeconomic impact). With **over 400 manufacturing sites across Europe**, more than 190.000 employees and an investment of up to 17% of their turnover into R&D activities, the generic medicines industry is an important and growing industry of the future.

Generic medicines deliver Sustainability

Generic medicines truly ensure access to high quality, safe and effective treatments for European patients which is essential for the well-being of our population. Incredibly, generic medicines only take up a very small part of the healthcare budget. **More than 62% of prescriptions** of dispensed medicines in Europe are generic

yet they account for just **29% of the total expenditure on medicines**. Without competition from generic medicine manufacturers, this level of access would cost Europe an additional €100 billion every year. For these reasons, it is therefore essential to foster a dynamic and competitive generic manufacturing sector in Europe.

The Generic medicines industry is committed to Partnership

To ensure that all patients get access to the medicines they need, our industry is committed to working with the healthcare community and with policy makers to create predictable and competitive pharmaceutical markets in Europe. Our association is therefore engaged in stakeholder and regulatory dialogues to provide objective and accurate information to improve access to high quality medicines.

2. About us

The Generic Medicines Group is a sector group of Medicines for Europe, representing the generic medicines developers and manufacturers, which provide high-quality cost-competitive medicines to millions of patients in Europe and around the world. Over 400 manufacturing and research & development sites across Europe produce your essential medicines, employ over 190.000 employees and invest up to 17% of their turnover into R&D activities. Generic medicines account today for **67% of all dispensed medicines but for only 29% of the pharmaceutical expenditure in Europe. In other words, generic medicines only account for 2-4% of total healthcare costs**. Without generic medicines, Europe would have had to pay €100 billion more in 2014 to get the same level of access to treatment as we have today. The European generic medicines industry vision is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership. For more information please follow us at www.medicinesforeurope and on Twitter [@genericsEU](https://twitter.com/genericsEU).

3. Mission and Vision

MISSION: To provide access to high-quality cost-competitive medicines to European patients.

VISION: Through partnership with key EU stakeholders, the generic medicines industry aims to increase access to medicines without increasing the overall treatment cost.

4. Definition

A generic medicine is developed to be the same as a medicine that has already been authorised (the 'reference medicine'). It contains the same active substance as the originator medicine, and it is used at the same dose to treat the same disease as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine.

A generic medicine is marketed in compliance with patent law. It is identified either by its internationally approved non-proprietary scientific name (INN) or by its own brand name. Generic medicines are widely used in many EU countries in cost-effective treatment programmes, and are increasingly prescribed by doctors as effective alternatives to higher-priced originator pharmaceuticals.

Key Therapeutic Areas Covered by Generic Medicines

Key Areas treated with sustainable generic medicines		
Cancer	Asthma	Parkinson's Disease
Diabetes	Osteoporosis	Epilepsy
Depression	Gastro-intestinal Disorders	Rheumatism
High Cholesterol	Viral Infections	Pain Relief
High Blood Pressure	Bacterial Infections	Inflammation
Allergies	Migraine	Skin Disease
Alzheimer Disease	HIV/AIDS	Contraceptives

Between 2005 and 2015, twice as many patients have been treated across different disease areas including **hypertension, epilepsy, gastro-intestinal disorders, mental health, high cholesterol and diabetes**, with no impact on treatment costs (IMS data). Where a generic medicine is based on an originator product, it can treat exactly the same condition with the same high level of quality, safety and efficacy.

Glossary

Bioequivalence: when compared scientifically, the generic medicine and the originator product demonstrate essentially the same rate and extent of biological availability of the active substance in the body when administered in the same dose. In simple terms, the generic medicine and the original product must be equally effective

Generic medicine: a generic medicine is developed to be the same as a medicine that has already been authorised (the 'reference medicine'). It contains the same active substance as the originator medicine and it is used at the same dose to treat the same disease as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine.

Medication adherence: the extent to which patients take medication as prescribed by their healthcare providers.

Quality Medicines are medicines that are free from defects, deficiencies and significant variations. In order to ensure the quality of medicines, the manufacturing of active substances, ingredients and medicinal products need to comply with the highest standards of excellence. Moreover the product also needs to be stable, which means that the quality needs to be ensured at least until the expiry date.

Safe Medicines are medicines that do not cause unacceptable harm. In order to guarantee the safety of medicines, pharmaceutical companies perform extensive studies before the medicinal product is accepted in the market. Moreover through their pharmacovigilance system, companies perform post-marketing safety surveillance of their products on the market.

A medicinal product is effective when it can alter the natural history of a disease for the better. For generic medicines the efficacy of a medicinal product is shown by establishing bioequivalence. Bioequivalence means that, when compared scientifically, the generic medicine and the originator product demonstrate essentially the same rate and extent of biological availability of the active substance in the body when administered in the same dose. In simple terms, the generic medicine and the original product must be equally effective.

Did you know?

- Bioequivalence is the key factor in creating a generic medicine.
- A generic medicine provides the same quality, safety and efficacy as the original brand name product.
- A generic medicine undergoes strict scrutiny before it is licensed and given market approval by the European or national medicines authorities.
- Generic medicines bring down the price of originator drugs through market competition.
- Without generic medicines, Europe would have had to pay 100Bn euros more in 2014 for its medicines.
- Generic medicines improve the cost-effectiveness of existing therapies.
- Generic medicines increase patient access to high-quality medicines and reduce expenditure while maintaining the same volume.
- Appropriate generic medicines policies can improve medication adherence.
- *The Generic Medicines Group* is a leading partner for better healthcare for all EU citizens.
- Our members are devoted to primary care medicines which represent 80% of healthcare spending.
- Generic medicines increase patient access to therapies by driving competition in the market.
- Generic medicines manufacturers invest up to 17% of their turnover in research and development.
- Generic medicines are the first line treatment for most chronic diseases such as diabetes, high cholesterol or hypertension.
- 80% of the costs in healthcare systems today are linked to chronic disease.

5. Contact Us

If you want to learn more about biosimilar medicines, you can find us at www.medicinesforeurope.com and on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU).

ANNEX

FACTSHEETS

factsheet | About Medicines for Europe



About Medicines for Europe

Medicines for Europe (formerly EGA) represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 190,000 direct employees at over 400 manufacturing and R&D sites in Europe, and invest up to 17% of turnover invested in R&D.



Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients.

For more information please follow us at www.medicinesforeurope.com and on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU).

The Generic Medicines Group



The Generic Medicines Group is a sector group of **Medicines for Europe**, representing the generic medicines developers and manufacturers, which provide high-quality cost-competitive medicines to millions of patients in Europe and around the world. Generic medicines account today for 67% of all prescribed medicines but for only 29% of the pharmaceutical expenditure, or 2-4% of total healthcare costs, in Europe. The generic medicines industry has increased access to medicines by over 100% in 7 key therapeutic areas without increasing the overall treatment cost across Europe.

The Biosimilar Medicines Group



The Biosimilar Medicines Group is a sector group of **Medicines for Europe** representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 10 years of positive patient treatment experience and 20 products successfully launched, biosimilar medicines provide today a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.

The Value Added Medicines Group



The Value Added Medicines Group, a sector group of **Medicines for Europe** aims to rethink, reinvent and optimise medicines based on known molecules by bringing untapped innovation to improve care delivery. The Value Added Medicines Group adopts a complementary perspective compared to the other **Medicines for Europe** sector groups by tackling the targeted portion of patient needs that remain unmet to this day, delivering additional improvements to the healthcare community as a whole. Medicines for Europe Membership

MEMBER COMPANIES

3M

Accord Healthcare

Alfred E. Tiefenbacher

Alkaloid

Apobiologix

Camargo

Cinfa Biotech

CinnaGen

Cinfa Biotech

Consilient Health

DSM

Egis Pharmaceuticals

Farmoz

Formycon

Fresenius Kabi

Gedeon Richter

Glenmark

INFARCO

Insud Pharma

JGL

KRKA

Lupin

Medichem

Medochemie

Mylan

OJER Pharma

Oncomed

Polpharma

Samsung Bioepis

Sandoz

Stada

Sun Pharma

Synthon

Teva

Theranexus

ZENTIVA

AFFILIATE MEMBER COMPANIES

Acino Pharma

Anapharm Europe

Billev Pharma

Billev Pharma East

Cipla

Disphar

Farmaprojects

JSC Farmak

Pharma Patent

PharOS

PARTNER MEMBERS

BioPharma Services Inc

Extedo

Pharma Medica Research Inc.

Sanaclis

NATIONAL ASSOCIATIONS FULL MEMBERS

AMMU (Ukraine)

AESEG (Spain)

APOGEN (Portugal)

AssoGenerici (Italy)

BGMA (United Kingdom)

BOGIN (Netherlands)

GEMME (France)

IEIS (Turkey)

IGL (Denmark)

Medaxes (BE)

Medicines for Ireland

Pro Generika (Germany)

PZPPF (Poland)

NATIONAL ASSOCIATIONS AFFILIATE MEMBERS

APM GR (Romania)

BGPharma (Bulgaria)

CAFF (Czech Republic)

CEA - PIA (HR)

FGA (Finland)

FGL (Sweden)

GE (Hungary)

GENAS (SK)

Intergenerika (Switzerland)

MAGYOSZ (HU)

OEGV (Austria)

VGA (LT)

Factsheet | The Generic Medicines Group



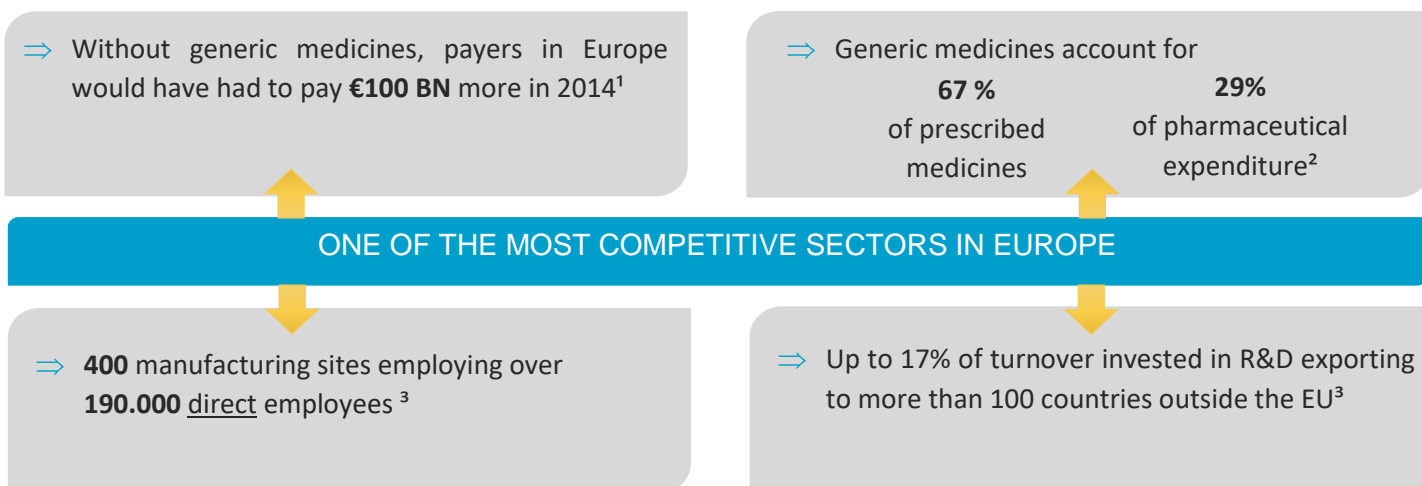
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Medicines for Europe vision is to provide sustainable access to high quality medicines for all European patients, based on 5 important pillars: **patients**, **quality**, **value**, **sustainability** and **partnership**.

For more information please follow us at www.medicinesforeurope.com and on Twitter [@genericsEU](https://twitter.com/genericsEU).

Generic medicines: the Cornerstone of European healthcare policy



¹ IMS Institute (2015) – The role of generic medicines in sustaining healthcare systems: a European perspective

² IMS Health, MIDAS Q4 2014

³ EGA Internal survey

Generic Medicines Group Membership

MEMBER COMPANIES

Accord Healthcare
Alfred E. Tiefenbacher
Alkaloid
Consilient Health
Egis Pharmaceuticals
Farmoz
Fresenius Kabi
Gedeon Richter

Glenmark
Insud Pharma
JGL
KRKA
Lupin
Medichem
Medochemie
Mylan

Polpharma
Sandoz
Stada
Sun Pharma
Synthon
Teva
Zentiva

AFFILIATE MEMBER COMPANIES

Acino Pharma
Anapharm Europe
Billev Pharma
Billev Pharma East

Cipla
Disphar
Farmaprojects
JSC Farmak

Pharma Patent
PharOS

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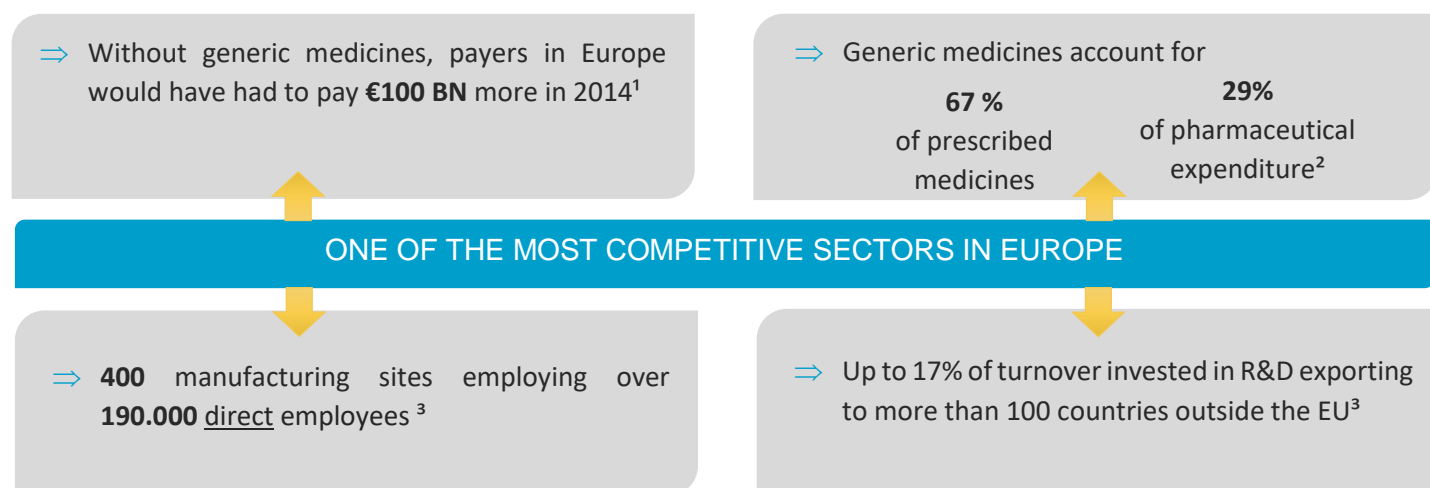
Factsheet | On Generic Medicines



What is a generic medicine?

A **Generic Medicine** is developed to be the same as a medicine that has already been authorised (the 'reference medicine'). It contains the same active substance as the originator medicine, and it is used at the same dose to treat the same disease as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine.

Generic medicines: the cornerstone of European healthcare policy



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³ EGA Internal survey

A tradition of quality, safety and efficacy

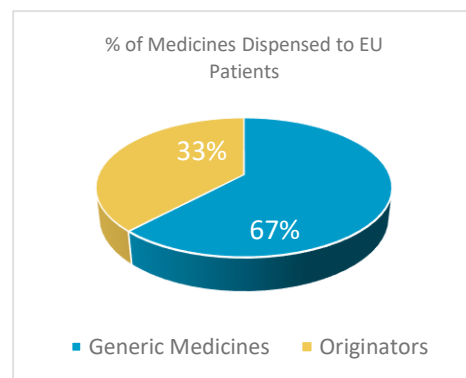
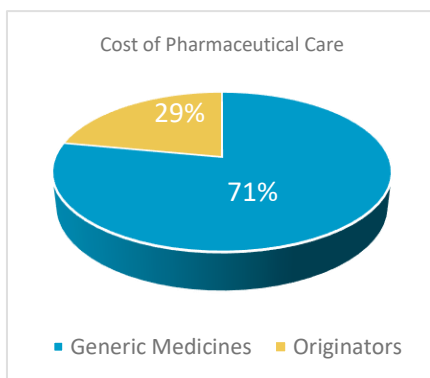
- ⇒ A generic medicine enters the market once the originator patent has expired.
- ⇒ Generic medicines and originator products are authorised to **the same standards of safety, quality and efficacy**.
- ⇒ Generic medicines are **bioequivalent** to the original product which means that they deliver **equal medical benefits to the patient**. Generic medicines are therefore interchangeable with the equivalent branded product.

Key Areas treated with sustainable generic medicines

Cancer	Asthma	Parkinson's Disease
Diabetes	Osteoporosis	Epilepsy
Depression	Gastro-intestinal Disorders	Rheumatism
High Cholesterol	Viral Infections	Pain Relief
High Blood Pressure	Bacterial Infections	Inflammation
Allergies	Migraine	Skin Disease
Alzheimer Disease	HIV/AIDS	Contraceptives

Ensuring equal access to healthcare for European patients

- ⇒ Generic medicines ensure equal access to frontline treatments for over 500 million European citizens.
- ⇒ The European generic medicines industry provides cost effective treatments for a large range of health conditions



The economic benefits of generic medicines

- ⇒ Generic medicines manufacturers also engage in innovation dedicating on average up to 17% of turnover invested in R&D
- ⇒ Generic medicines lead in pharmaceutical manufacturing in the Europe while creating a multi-supplier market.
- ⇒ Over 190 000 jobs in Europe.
- ⇒ 75% of generic medicines consumed in Europe are produced in Europe.
- ⇒ Emerging markets outside Europe provide EU manufacturers with major opportunities for export.

Source:
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf
 Source: EGA Internal survey 2014, IMS Institute (2015) – The role of generic medicines in sustaining healthcare systems: a European perspective



PRESENTATION (POWERPOINT)
VALUE OF GENERIC MEDICINES

Value of generic medicines

quality • patients • value • sustainability • partnership

Medicines for Europe Vision 2020 Our 5 pillars

Medicines For Europe
VISION



PATIENTS



QUALITY



VALUE



SUSTAINABILITY



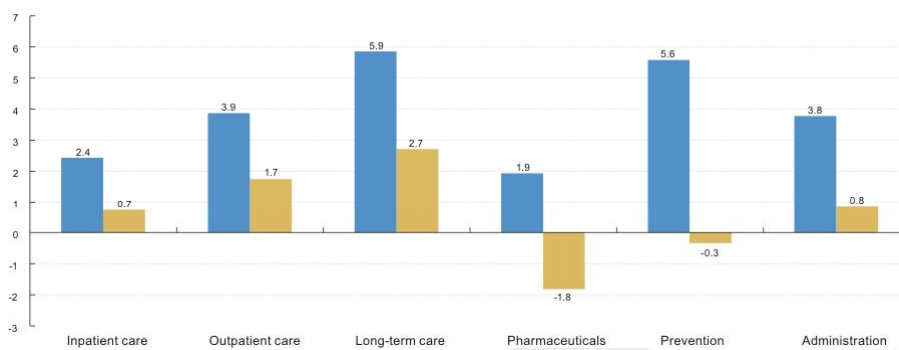
PARTNERSHIP

Pressure on EU budgets Reduction of healthcare spending

Growth rates of health spending for selected functions per capita, OECD average, 2005-2013

2005-09 2009-13

Average annual growth rates in real terms, %



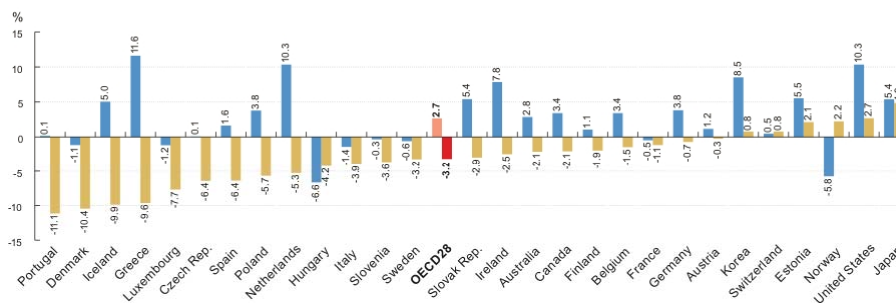
Source: OECD Health at a Glance (2015)

Reduction of healthcare spending Focus on pharmaceuticals



Average annual growth in pharmaceutical expenditure¹ per capita, in real terms, 2005-09 and 2009-13 (or nearest periods)

2005-09 2009-13



¹ Includes medical non-durables.

Source: OECD Health at a Glance (2015)

An ageing population: Major EU social and economic challenge



Modern lifestyle and an ageing population increase prevalence of chronic disease

129 Million patients



2014

+50%

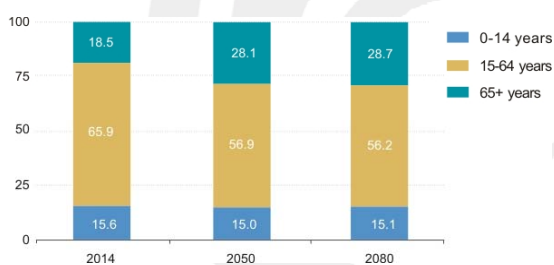
Population
over 65 years

191 Million patients



2050

Population Structure by Major Age Groups
EU28, 2014-2080 (percentage of total population)



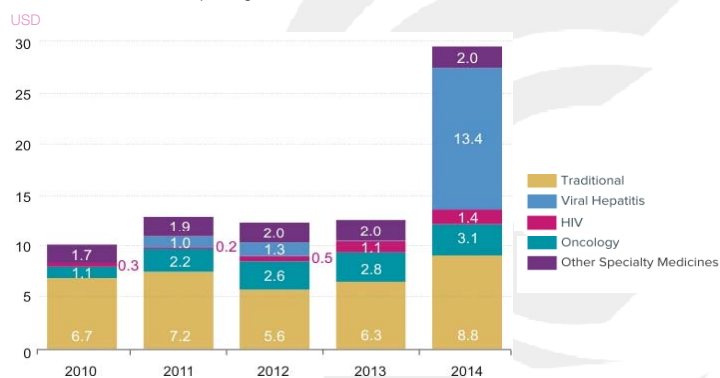
Source: Eurostat Population Statistics

A surge in innovation: Major EU social and economic challenge

Global spending on new brand medicines has more than doubled in 2014 and is 2.6% of global pharmaceutical spending

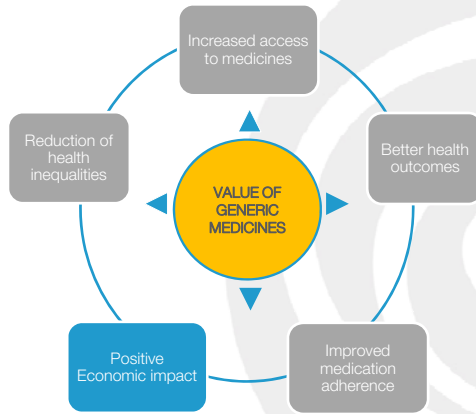


Global New Brand Spending Growth USD Bn



Source: IMS Health, R&D Focus, May 2015; MIDAS, Q4 2014, constant USD

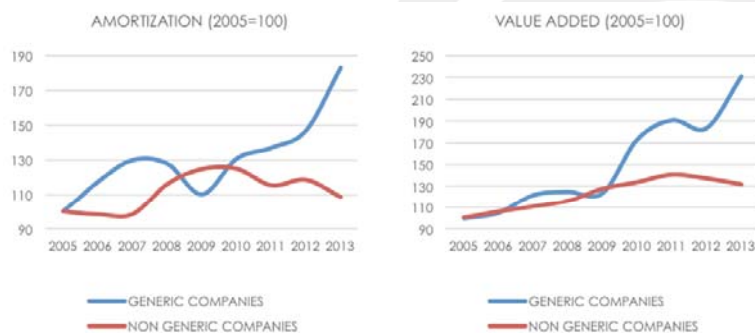
Generic medicines are key to EU healthcare sustainability



Contribution to overall economy

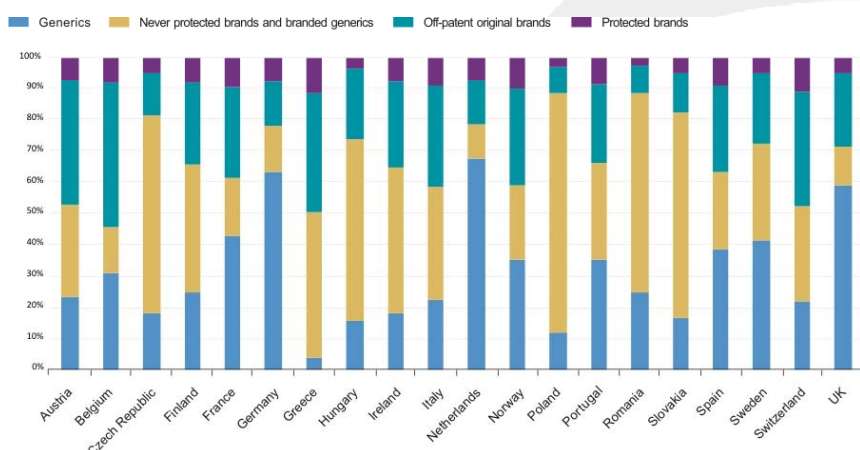
Generic medicines industry Activation of investments, employment and value added

Depreciation and value added trends – 2005-2013 (Italy)



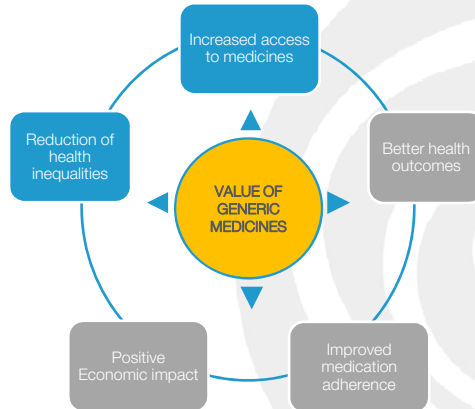
Still considerable opportunities to increase uptake throughout Europe

Protected and off-patent marked share (volume) by country, June 2015



Source: IMS Health, MIDAS, Q2 2015, retail and hospital channel

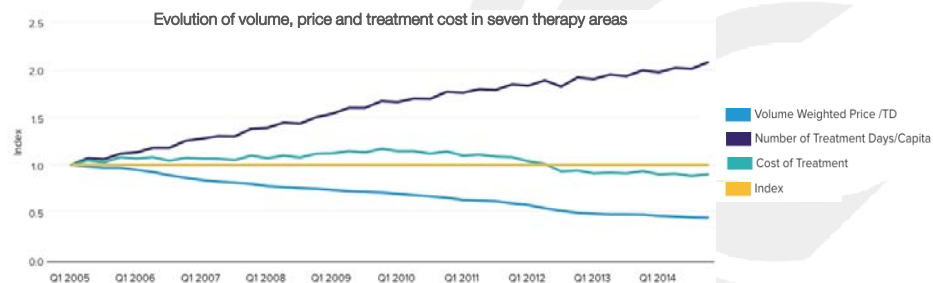
Generic medicines are key to EU healthcare sustainability



Generic medicines increase patient access



Twice as many patients treated... without an impact on treatment costs



Selected therapy areas: Hypertension, epilepsy, gastro-intestinal disorders, mental health, high cholesterol and diabetes.
Source: IMS Institute for Healthcare Informatics. The Role of Generic Medicines in Sustaining Healthcare Systems. June 2016.

Benefits accrue in different ways across countries

Increased access to medicines delivers long-term benefits to society and to healthcare providers

	Time period 2005 to 2014			
	Country	Price (€/TD)	Volume (TD/cap)	Treatment Cost
Decline in overall treatment cost	Germany	-62%	153%	-7%
	UK	-64%	143%	-13%
	France	-51%	40%	-31%
	Italy	-53%	121%	-9%
	Ireland	-59%	148%	-9%
	Sweden	-69%	108%	-40%
Stabilisation of overall treatment cost	Spain	-50%	109%	0%
	Czech	-53%	132%	2%
	Austria	-49%	133%	14%
Increased access in under-served groups	Slovenia	-60%	152%	-30%
	Poland	-51%	192%	33%
	Slovakia	-63%	207%	0%

Source: IMS Health, MIDAS, Q4 2014; OECD Population statistics
Selected therapy areas: angiotensin II antagonists, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics.

Generic medicines reduce healthcare inequalities

Cost-efficiency gains

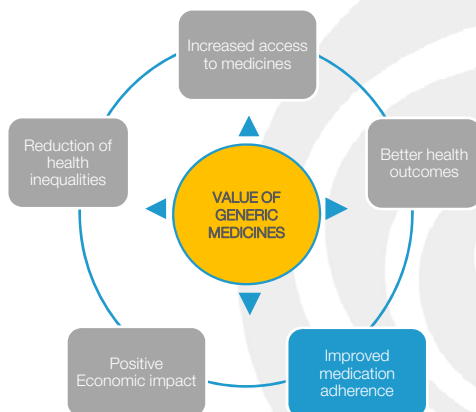
Investment in health

Reduce **healthcare expenditure** without compromising **health outcomes**

Improve **health outcomes** through better patient access without increasing **health expenditure**

Source: Kaló, Z et al. (2014). Investment aspects of generic drug policies in countries with severe resource constraints. Poster presented at ISPOR Annual European Congress in Amsterdam

Generic medicines are key to EU healthcare sustainability



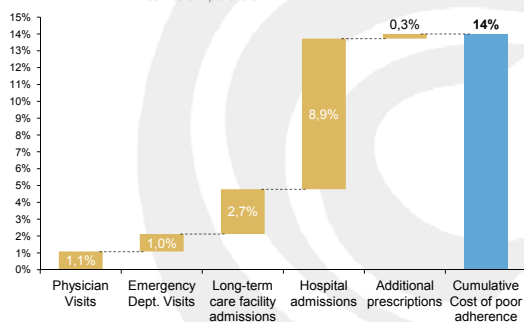
Better adherence will improve health outcomes and lead to a positive economic impact

Lack of adherence is estimated to cost the European governments €125 billion / year



Avoidable cost for the National Healthcare System

Additional cost of poor adherence compared to the total healthcare expenditure



Source: New England Healthcare Institute: A system-wide approach to improving patient medication adherence for chronic disease (2009)
Note: €125bn/year is an A.T. Kearney estimate based on US avoidable cost data

Better adherence will improve health outcomes and lead to a positive economic impact

Appropriate generic medicine policies can improve adherence

Generic medicines positively influence adherence in systems with lower co-payment for generic medicines

The pharmacist's role in ensuring patient understanding and comfort with medication through accurate information and dialogue is crucial to maximize adherence when substituting

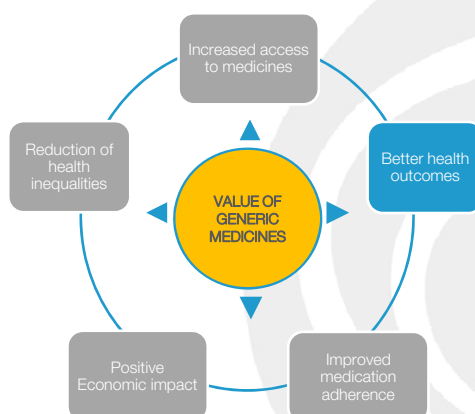
Adherence is linked to patient co-payment*
Italian patients receiving generic amlodipine, with lower patient co-payment, were more adherent compared to branded amlodipine**

Impact of substitution
Adherence of Dutch patients, which have one designated pharmacy, was not influenced by substituting generic hypertensive medicines for a branded medicine**

*Co-payment exists across Europe, including but not restricted to the following countries: Belgium, Bulgaria, Finland, Hungary, Ireland, Italy (regional), Portugal, Romania, Switzerland. (Source: EGA market review 2015)

**Source: IGES Study, Value of Generic Medicines, 2015

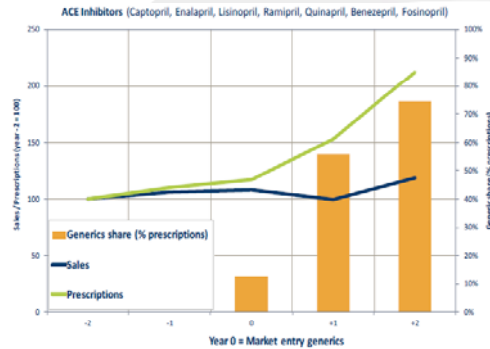
Generic medicines are key to EU healthcare sustainability



Better health outcomes - Hypertension



- Antihypertensive drugs reduce mortality in hypertensive patients
- 50% decrease in hypertension related mortality in DE (1998-2010)
 - Increased access and treatment rates
 - Better medicinal treatment options
 - Smoking reduction
 - Better hypertension control
 - Guideline implementation



Increased cost-effectiveness

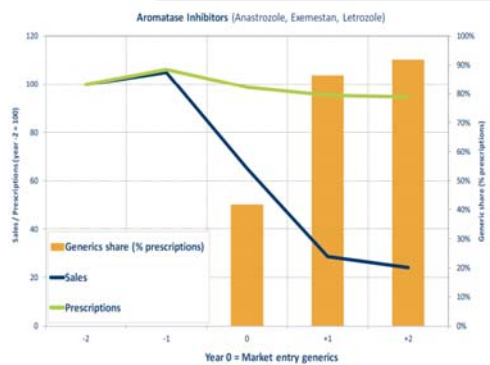
Source: IGES Study, Value of Generic Medicines, 2015

Source: IGES based on data in Schwabe/Patfrath (various years)

Better health outcomes - Breast cancer



- Adjuvant endocrine therapies: Over 15 years after treatment start, mortality is reduced by 1/3 and recurrence rates by 40%
- Breast cancer related mortality decreased since late 1980s
 - Improved treatment options
 - Increased access
 - Early detection programs



Decreased cost/QALY

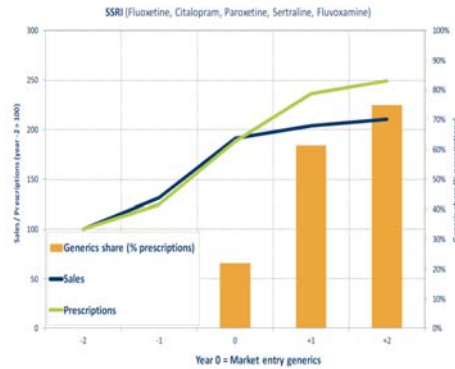
Source: IGES Study, Value of Generic Medicines, 2015

Source: IGES based on data in Schwabe/Patfrath (various years)

Better health outcomes - Depression



- Anti-depressants: More effective than placebo in treatment of severe depression
- 45% of suicides attributable to depression
- Mortality due to suicide decreased since 1980s
 - Improved treatment options
 - Improved psychotherapy
 - Increased access

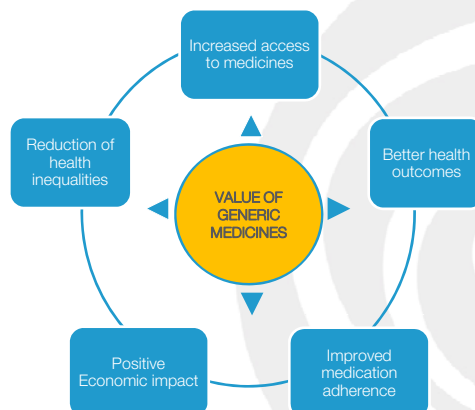


Facilitated continued increase of low treatment rates

Source: IGES Study, Value of Generic Medicines, 2015

Source: IGES based on data in Schwabe/Paffrath (various years)

Generic medicines are key to EU healthcare sustainability



REPORT

IGES REPORT: VALUE OF GENERIC MEDICINES

Value of Generic Medicines

Executive Summary of the EGA study
“Value of Generic Medicines”

for the
**European Generic and Biosimilar
Medicines Association**

Berlin, 15 December 2015

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Executive Summary

Generic medicines: Biggest contributor of the European drug supply and high savings potential – but not in all European countries

Generic medicines contribute substantially to European drug supply. In most European countries, the market share of generic medicines in volume terms is over 40% – in Germany, Europe's biggest pharmaceutical market, even about three quarters. Since generic medicines are more affordable than patented medicines, their market shares by value are significantly lower. This highlights the cost-reducing effects associated with the availability of generic medicines, to the benefit of healthcare systems. In recent years, average price reductions of up to 70% were recorded within two years after generic market entry. Generic medicines are therefore commonly attributed an (overall) economic value, resulting from the significance of the generics medicines industry for investment and employment in addition to the cost reduction of health systems.

In an international comparison, the consumption of generic medicines varies quite a bit. Market shares by volume and value differ significantly between European countries, due to different institutional and legal settings and policies to promote generic substitution. The potential savings from generic medicines are thus not entirely realized within Europe.

Focus: the value of generic drugs for patients

The present study, conducted by the IGES Institute on behalf of the European Generic and Biosimilar Medicines Association (EGA), reveals, beyond just the purely economic value, the patient-related value of generic medicines based on three selected drug classes: hypertension (antihypertensives), breast cancer (adjuvant endocrine therapies) and depression (antidepressants). For all of them, there is clinical evidence that patient benefit from pharmacotherapy. Parallel to increased, or at least continuous, utilization of drug treatments, the relevant population-based health-outcomes have improved. Based on data for Germany, the crucial role of patient access to generic medicines and of rapid market penetration is highlighted, both being the precondition for achieving cost savings as well as health impact.

Diseases caused by hypertension

There is comprehensive evidence on the clinical benefit of **antihypertensives** due to lowering blood pressure and, consequently, to reducing the risk of strokes, coronary heart disease, heart failure and cardiovascular death. These positive effects are largely independent of the drug classes employed and whether it is an originator or a generic medicine.

Utilization of hypertension drugs has increased considerably over the last decades in Europe. At the same time, hypertension-related mortality has decreased significantly in EU countries (in Germany, for example, by about 50% between 1998 and 2010). One of the designated causes for the observed mortality decline is better medical treatment options, though other factors also contributed (such as smoking reduction, better hypertension control, guideline implementation).

For Germany, it could be shown that treatment utilization with antihypertensive drugs increased significantly after generic market entry, combined with rapid generic market penetration. Sales, in contrast, kept almost stable, indicating that considerably more patients had been treated within two years after the respective generic market entry without noticeable rise in cost, suggesting an increase in cost-effectiveness. Correspondingly, based on US-data it was estimated that generic substitution brings cost of hypertension control medications to gain an additional QALY¹ down by about 85%.

Breast Cancer

Based on current clinical evidence, the use of **adjuvant endocrine therapy** for breast cancer reduces the mortality rate by a third and the recurrence rates by almost 40% over a period of 15 years after treatment start. The clinical benefit differs between drug classes, yet primarily depending on the patient's menopausal status.

Utilization of adjuvant endocrine therapies increased or remained steady over the past decade, while breast-cancer-related mortality decreased in European countries, in many of which by about a quarter up to a third. Besides improved treatment options, early detection programs have also contributed to this reduction.

German data show extraordinary rapid generic penetration with volume market shares reaching, on average, more than 90% two years after generic market entry. As a result, sales declined substantially while treatment utilization remained almost at constant levels, suggesting significantly increased cost-effectiveness. This has been confirmed by study estimations, showing that price reductions by generic medicines which can reasonably expected lead to a decline of incremental cost per QALY (aromatase inhibitors vs. selective estrogen receptor modulators) ranging from nearly 30% to almost 90%.

Depressions

Clinical evidence for **antidepressants** with regard to treatment goals of remission, prevention of relapse, and prophylactic treatment is inconclusive. Antidepressant drugs seem to be more effective than placebo in treatment of major depression, whereas in patients with mild depressive episodes, they have often proved not to

¹ Quality Adjusted Life Year, key indicator for evaluating a life year in relation to health.

be more effective than placebo. Different substances are generally equally effective, yet, there are significant differences in toxicity and side effects.

Utilization of antidepressants treatment has still increased considerably over the last decade, as treatment of depression has become socially more acceptable and the willingness to seek treatment has increased. Unlike the other two disease groups, no comparable obvious indicators for measuring health outcomes are available for depression. A possible indicator is the suicide rate as a type of depression-related mortality. In fact, death rates caused by suicide have decreased significantly in many European countries. However, evidence on whether and how much antidepressants contribute to a reduction of suicide is ambiguous. Alternative health benefit indicators with regard to antidepressant treatment (such as reduction of work disability) have been rarely considered yet. The fact that treatment utilization has increased substantially regardless of relatively limited clinical and population-based evidence on health benefits is attributable to the large share of still untreated or inadequately treated patients and, thus, to unmet medical need.

Besides increasing cost-effectiveness, patient access to generic medicines may improve **treatment adherence** and, thus, cause positive health impact. High(er) co-payments for branded medicines, but also education measures for patients referring to generic substitution support a positive impact of generic medicines on patient adherence. However, the process of generic substitution is also prone to negatively influence patient adherence, as the controversial discussion about the effects of individual rebate contracts on patient compliance in Germany illustrates. Correspondingly, findings for the three selected drug groups are inconsistent.²

² For generic antihypertensive drugs, both positive and negative influences on adherence to therapy have been found. For generic aromatase inhibitors, studies from the USA show positive correlations with treatment adherence, while higher co-payments led to therapies not being adhered to. Finally, for antidepressants there are also contradictory findings. US studies have shown that the use of generic drugs is associated with a reduced risk of treatment interruption, but that dropout rates do not differ significantly between patients who use brand drugs versus generics (SSRI, SNRI).

Conclusion: Generic medicines contribute to improving healthcare

The three selected drug classes illustrate – based on the German example – different variations on how generic medicines can help to improve healthcare: Rapid and high market penetration of generic medicines

- ◆ provides access of substantially more patients to pharmacotherapy at the same spending levels, and thus higher cost effectiveness (e.g. anti-hypertensive),
- ◆ slows down expenditure at equal treatment rates, thus additional costs per QALY decrease (e.g. adjuvant endocrine therapy),
- ◆ facilitates continuous increase in pharmacotherapy via expenditure containment and reduces health care deficits due to low treatment rates (e.g. antidepressants).

Further research should be intensified with regard to the patient-related value of generic medicines. This involves, first, detailed estimation of improved cost-effectiveness for further indication areas or patient groups. Beyond that, the specific contribution of generic medicines to the reduction of unmet medical need, or of the number of untreated or inadequately treated patients respectively, could be examined in more detail. Finally, additional health outcome indicators related to (generic) drug therapy should be considered in future research, such as the reduction of work disability.

[Full report here](#)

REPORT

IMS REPORT: THE ROLE OF
GENERIC MEDICINES IN
SUSTAINING HEALTHCARE
SYSTEMS: A EUROPEAN
PERSPECTIVE

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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Full report here

INFOGRAPHIC

KEY FIGURES ON GENERIC MEDICINES



67%
OF **DISPENSED**
MEDICINES

29% +
OF PHARMACEUTICAL **EXPENDITURES**



-€100BN
LESS SPENDING
THROUGH GENERIC COMPETITION

+400 
MANUFACTURING SITES
IN THE EU



HIGH QUALITY MEDICINES
TO OVER
500 MILLIONS
PATIENTS

Cardiovascular | Hypertension
Diabetes | Depression
Epilepsy | Mental disorder
Gastro-intestinal



+100% **PATIENT ACCESS**
OVER 10 YEARS

+190,000
EMPLOYEES



UP TO
17%
R&D INVESTMENT



INFOGRAPHIC

VALUE OF GENERIC MEDICINES

INCREASED PATIENT ACCESS



HYPERTENSION



MORE PATIENTS TREATED
with
SAME EXPENDITURE

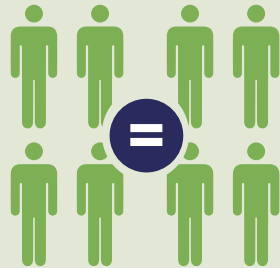


PATIENT-RELATED VALUE

- IMPROVED MEDICATION ADHERENCE
- BETTER PATIENT HEALTH OUTCOMES



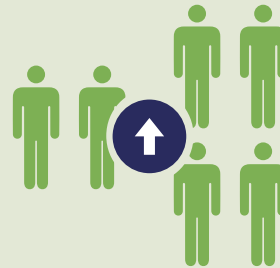
BREAST CANCER



SAME NUMBER OF PATIENTS TREATED
with
LESS EXPENDITURE



DEPRESSION



MORE PATIENTS TREATED
with
SMALL EXPENDITURE INCREASE



OVERALL ECONOMIC VALUE



MAIN SUPPLIER OF MEDICINE
IN EUROPE



HEALTHCARE BUDGET
SUSTAINABILITY



POSITIVE CONTRIBUTION TO EUROPEAN
ECONOMY (JOBS & INVESTMENT)

INFOGRAPHIC

THE ROLE OF GENERIC
MEDICINES IN SUSTAINING
HEALTHCARE SYSTEMS: A
EUROPEAN PERSPECTIVE



THE ROLE OF GENERIC MEDICINES IN SUSTAINING HEALTHCARE SYSTEMS: A EUROPEAN PERSPECTIVE

HEALTHCARE BUDGET CHALLENGES

AGEING POPULATION

129 Million
patients >65 years



2014



191 Million
patients >65 years



2050

INCREASED INCIDENCE OF CHRONIC DISEASES



DIABETES



DEPRESSION



EPILEPSY



CARDIOVASCULAR
DISEASE



HYPERTENSION

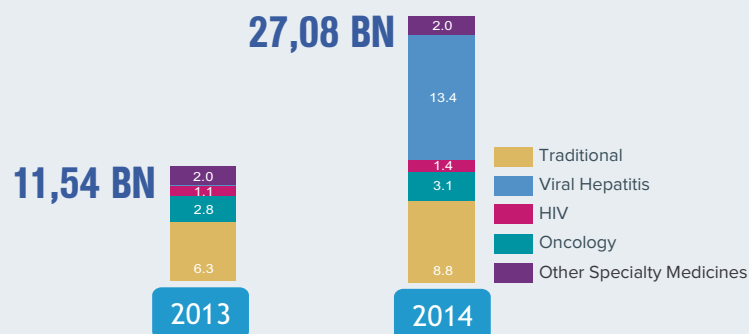


ASTHMA/COPD



GASTRO-INTESTINAL
DISEASE

HIGH COST OF NEW MEDICINES



GENERIC MEDICINES CONTRIBUTION

ECONOMIC VALUE



56%
OF VOLUME SUPPLIED
BY GENERIC MEDICINES



75%
OF GENERIC MEDICINES
ARE MANUFACTURED
IN EUROPE



-€100BN
WITHOUT GENERIC MEDICINES, GOVERNMENTS WOULD
HAVE HAD TO PAY AN ADDITIONAL €100BN IN 2014

INCREASED PATIENT ACCESS



TWICE AS MANY PATIENTS TREATED



NO IMPACT ON BUDGET

BENEFITS FOR COUNTRIES

