2011 Market Review (Part 2)
The European Generic Medicines Markets

European Panorama

2011 Market Review (PART II) | The European Generic Medicines Markets - European Panorama
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Foreword

The EGA Health Economics Committee is pleased to release the 2011 Market Review, part II: ***A European Panorama of the Generic Medicines Pharmaceutical Markets.***

This document is intended to provide EGA members with updated data on a European Panorama of Price & Reimbursement Systems for Generic Medicines in 2010.

This second part of the Market Review compiles the information sourced from tables of the Market Review, Part 1. It covers a set of European countries in relation to the pricing and reimbursement policies both from the demand and the supply sides ranging from generic medicines pricing systems to general information about generic medicines. It reflects the environment in which generic medicines evolve after marketing authorisation until full market access.

This document aims to provide the reader with a clear picture of different policies that face the European Generic Medicines Industry.

The EGA would like to sincerely thank all of its members for their support and invaluable contribution to the 2011 Market Review.

Greg Perry
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EXECUTIVE SUMMARY

The 2011 Market Review presents a detailed analysis of the European generic medicines pharmaceutical markets. This year the report covers 20 European countries: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Turkey and the United Kingdom. This document is intended to provide EGA members with updated data on a European Panorama of Price & Reimbursement Systems for Generic Medicines in 2010.

It has 10 main sections with detailed market information that focuses on the Pricing & Reimbursement Systems across Europe, paying particular attention to the key aspects that impact the dynamics of the generic medicines pharmaceuticals market, such as:

• Generic Medicines Pricing Systems
This chapter will disclose information on the European trends on free pricing systems versus regulated pricing systems. It will also inform on actors involved in the process.

• Tendering or Tender-Like Systems
This section aims to give an overview of the analysed countries that have a tender or tender-like system in the retail market. It will show the impact of such systems on the generic medicines industry.

• Reimbursement Systems
This part will focus on providing a picture of the reimbursement systems employed across the European countries surveyed.

• Patient Co-payment
This chapter will give information about what patient co-payment is and how such a system is implemented in the European countries surveyed.

• Patient Use of Generic Medicines
This chapter throws light on how patients and the general public perceive generic medicines. As a result, we will learn more about the different means used by governments to promote the use of generic medicines.

• Generic Medicines Prescribing
In this part, we learn more on how doctors can be encouraged to prescribe generic medicines and what tools are used as promotional incentives.

• Generic Medicines Substitution
This chapter will focus on pharmacist's dispensing habits with regard to substitution and the existing policies in place in the European countries surveyed.

• Generic Medicines Distribution
This chapter aims to cover the mechanism governing the distribution of medicines from the manufacturer to the wholesaler and on to the pharmacists. Some charts will be dedicated to the role of each of these stakeholders within the supply chain.

• Market Authorisations
This part will try to answer how generic medicines succeed in obtaining the market authorisation to be marketed and indicate some hurdles that can occur in this process.

• General Information about Generic Medicines
This chapter describes the level of initiatives taken by Governments to increase patient and the general public's awareness on generic medicines use.

Since the first Market Review edition, the EGA Health Economics Committee has been trying to work towards EGA members' needs, both in terms of regulatory issues and market access perspective. Therefore, three sections have been added this year:

- Tendering or Tender-Like Systems
- Generic Medicines Distribution
- General Information about Generic Medicines

Each section will follow the same format:

- A brief highlight on the situation or recent evolution of the section analysed
- Presentation of the section's charts with a brief interpretation of the key figures
- Key points of the section

From this document, the reader will learn more about the different European systems related to generic medicines pricing and reimbursement, and will be able to appreciate the different policies of the countries surveyed.

INTRODUCTION

Since the last edition of the Market Review in 2007, there have been dramatic changes impacting the sustainability of the European generic medicines industry. From a pharmaceutical market perspective, the patent cliff that started in 2007, to reach its peak in 2011-2012, has fuelled the growth of the generic and biosimilars medicines market, resulting in higher savings for governments.

Whilst most European governments have continued to cut prices of medicines and exploit short-term cost-suppression tools, the generic medicines industry has held fast to providing quality treatments to EU citizens while stimulating competitiveness and sustainability of healthcare systems.

The EGA estimates that generic medicines savings have reached €30 BN in savings per year, however, a recent IMS report[1] suggested that this value was rather conservative and that it was possible to achieve additional thousands of billions of Euros in savings.

At the same time, governments and payers, under pressure, due to the recent financial crisis and the increasing expenditure of health budgets, have initiated intense campaigns aimed at short term savings, with price cuts introduced mostly in the Southern markets and tendering or tender-like systems in the Northern markets.

While in the Southern markets price cuts were implemented in waves that saw generic medicines markets decrease to half of their original value, in the Northern markets, with tendering and tender-like systems, the value of the generic medicines market dropped dramatically. In both Southern and Northern regions, generic medicines volumes remained practically equal, thereby leading to unprecedented pricing pressure forcing generic medicines companies to leave the market.

Governments have been focused on achieving short-term savings rather than implementing measures that from a supply-side perspective would guarantee generic medicines immediate market access and end any type of linkage that blocks or limits them. Neither are there efforts to increase demand-side incentives for doctors to prescribe, pharmacists to dispense and patients to ask for generic medicines.
On the political front, developments have been equally important with the European Commission Pharmaceutical Sector Inquiry[2], that has proven that in a number of cases, generic medicines market access has been delayed – or in extreme cases blocked for several years – due to strategies implemented by originator companies. In the Pharmaceutical Sector Inquiry these actions were described under a framework name, the "tool box". This consisted of patent strategies, frivolous litigation, lobbying of authorities, lifecycle strategies and misinformation to the public.

The EGA has supported the European Pharmaceutical Sector Inquiry and has campaigned on the importance of a quick implementation of the sector inquiry recommendations. As a first result, the European Commission is now planning to review the transparency issues that have a major impact on the national pricing & reimbursement systems.

The EGA will support the Sector Inquiry recommendations:

a) immediate/automatic price and reimbursement for generic and biosimilar medicines;
b) a ban on patent linkage in all regulatory procedures;
c) a requirement for pricing and reimbursement agencies not to look at bio-equivalence and efficacy;
d) a requirement that third party submissions should be well documented (burden of proof), made transparent for the generic medecines company and should not delay the application.

Despite all the hurdles that the European generic medicines industry is currently facing, it continues to increase their fundamental role in the healthcare equation, ensuring sustainability and increasing patient access to affordable treatments.

Another important issue is the ageing population which is expected to continue to increase dramatically over the next few years, and with governments under pressure to continue to deliver free or partially-free healthcare to their populations, the generic medicines industry is more than ever part of the solution.

[1] IMS. INTELLIGENCE. APPLIED. Alan SHEPPARD, Generic Medicines: Essential contributors to the long-term health of society, SECTOR SUSTAINABILITY CHALLENGES IN EUROPE
[2] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

At the same time, the role of the European generic medicines industry has expanded in other areas than simply the pharmaceutical ones. Today the industry provides more than 150 000 jobs, with more than 1000 companies undertaking product development and manufacturing around Europe, while successfully exporting to all regions of the world. This has transformed the industry into a major contributor to the European economy.

Another important milestone in the recent history of the European generic medicines industry are the recent successes related to the launch of the first biosimilars worldwide. This is becoming a leading industry with the support of the European Commission, paving the way for a correct regulatory framework for biosimilars. Today, biosimilars have already achieved savings of 1,4 Bn Euros and they are expected to increase their contribution to European healthcare in the near future.

In this context the EGA Market Review assumes a crucial role for the gathering of information relating to market dynamics, market access and pricing and reimbursement, all of which impact the success of generic medicines companies in the market.
Part two of the EGA Market Review 2011 presents a detailed overview of the current European panorama in terms of pricing and reimbursement systems.

Some of the key conclusions of the Market Review, Part II are noted below:

1. Generic Medicines Pricing Systems
- A vast majority, 80%, of the surveyed countries have a regulated pricing system
- Within price-regulated systems, prices are based on different options: average of EU countries, % below the originator or maximum price
- The most common mechanisms used to regulate prices are: % below the originator (37%) and a maximum price (31%)

2. Tendering or Tender-Like Systems
- 70% of the countries reviewed have held through discussions about implementing a tendering system
- The driving forces for tendering systems mostly come from health insurance funds and government
- Concerning price negotiation, three options are possible: by active substance, by product or by therapeutic indication

3. Reimbursement Systems
- The vast majority of countries will base their reference price on the lowest priced medicines
- Within the reference pricing system, the price is established either by: active substance, pharmacological class or therapeutic class
- 77% of the surveyed countries have a positive list in place for the reimbursement system

4. Patient Co-payment
- 95% of the analysed countries have a patient co-payment system in place.
- The two most widespread mechanisms for the patient co-payment are % of cost of medicines and difference above referenced price
- 87% of the revised countries do not differentiate between originator and generic medicines within the framework of the co-payment system

5. Patient Use of Generic Medicines
- 60% of the European countries analysed have carried out consumer surveys to ascertain the general opinion of patients with regard to generic medicines
- In 87% of the European countries reviewed, the general public have a positive perception of generic medicines
- The most common means of communicating information about generic medicines is through websites

6. Generic Medicines Prescribing
- 65% of the European countries surveyed encourage doctors to prescribe generic medicines
- Doctors can be encouraged to prescribe generic medicines by budgetary restrictions or budgetary incentives. In parallel, some of the countries may have other specific measures to enhance generic medicines prescribing from doctors
- In 68% of the systems analysed, doctors are assisted in generic medicines prescribing mainly through the use of a computerised database

7. Generic Medicines Substitution
- In 75% of the countries analysed, substitution is allowed
- Generic medicines substitution is compulsory in 40% of the countries analysed
- Pharmacists' response to substitution:
  a. when a doctor prescribes a branded original product, in 60% of the countries analysed, the

pharmacist will dispense a generic medicine without advice from a doctor

b. when a doctor prescribes a medicine using the INN, the pharmacist will, in 24% of the cases reviewed, prescribe either any generic medicine, or the cheapest generic medicine

c. when a doctor prescribes branded generic medicines, in 28% of cases the pharmacist will dispense any generic medicine, without reference to a doctor

- In 93% of the countries surveyed, the patient has to be informed about substitution
- The large majority, 89%, get no reward for prescribing generic medicines

8. Generic Medicines Distribution

- In 68% of the countries reviewed, the distribution of generic medicines goes through industry/ wholesaler/ pharmacy
- In almost 50% of cases, the wholesaler is considered as a logistical partner in the generic medicines distribution chain;
- In 30% of cases, the wholesaler may be viewed as a business partner and in the remaining 20% of cases the countries under review have their own peculiarities with regard to the role of the wholesaler

9. Market Authorisations

- 53% of European countries have the same process for pricing and reimbursement of generic medicines
- 47% of the European countries analysed have separate processes for pricing and reimbursement of generic medicines
- In 53% of the countries surveyed, it is permissible to have a generic medicine price granted during the patent/SPC period
- 50% of the countries analysed permit generic medicine reimbursement during the patent/SPC period

10. General Information about Generic Medicines

- Governments from 68% of the countries surveyed implemented measures to stimulate the prescribing and dispensing of generic medicines in 2010

GENERIC MEDICINES PRICING SYSTEMS

To control health expenditure, European Governments implement different types of regulations or systems on the supply side directly linked to the pricing and reimbursement of medicines.

The focus of this chapter will be on pricing regulation and the types of mechanisms that are used by the vast majority of European countries to restrict medicine prices.

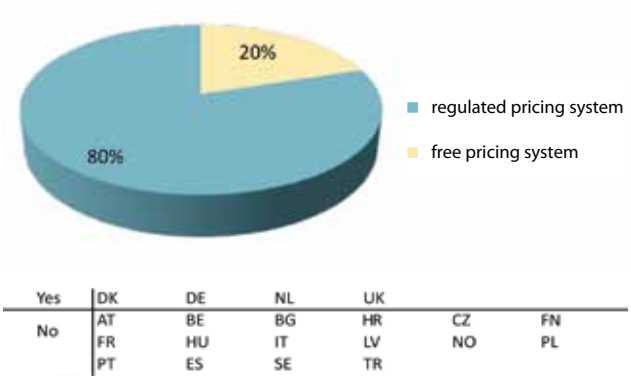
In countries where there is a dynamic pricing system in place, generic medicines prices are not controlled through regulations and those countries use other mechanisms to control price levels.

In countries with price regulation, the generic medicine price is normally linked to a reference product or other mechanism that will place a limit on the price level.

Finally, it is important to remember that part of this mechanism imposes a permanent linkage until the end of the lifecycle of the generic medicine.

Among the 20 countries surveyed, 20% have in place a free pricing system compared with 80% having in place a regulated pricing system. The following chart 1.1 illustrates generic medicines pricing system schemes in place in the European countries analysed.

1.1 Generic Medicine Pricing System: Free Pricing System vs. Regulated Pricing System



Yes	DK	DE	NL	UK		
No	AT	BE	BG	HR	CZ	FN
	FR	HU	IT	LV	NO	PL
	PT	ES	SE	TR		

In countries where price regulations are in place, 5 schemes are possible for the purposes of price determination:

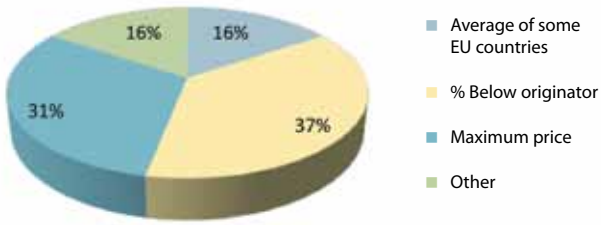
- The average price in selected EU countries
- % below the originator
- Maximum price
- Negotiable
- Other

Each country may have its own combination of these different options.

Many of the countries (37%) set prices by ensuring they are a given percentage below the price of the originator product. It ranges from 20% below the originator for Italy to 80% below for Latvia.

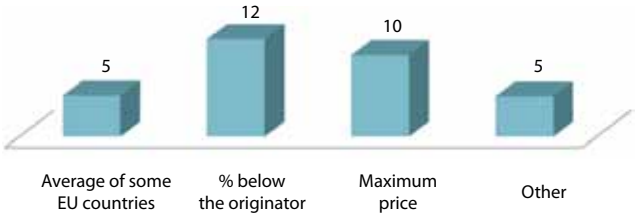
Another large percentage of countries (31%) set a maximum price for generic medicines, this being for instance the case in Austria, Bulgaria, Croatia, Czech Republic, Netherlands, Norway, Poland Spain, Sweden, and Turkey.
The following charts 1.2 & 1.3 give a clear picture of the weight of the different options concerning the setting of generic medicines prices in a price regulated system.

1.2 Mechanisms Used in a Regulated System



The following graph 1.3 shows the exact number of the different mechanisms used per country analysed.

1.3 In the Countries With Price-Regulated Systems, Prices are Based on:



KEY POINTS

- 80% of the surveyed countries have a regulated pricing system
- 20% of the countries reviewed have implemented a free pricing system
- Within price-regulated systems, prices are based on different options: average of EU countries, % below the originator or maximum price
- The most common mechanisms used to regulate prices are: % below the originator (37%) and a maximum price (31%)

2 TENDERING OR TENDER-LIKE SYSTEMS IN THE RETAIL MARKET

Tendering or tender-like systems are well and widely known procurement tools that have been used in the vast majority of European countries as a normal procedure within the hospital sector.

With the increase in healthcare expenditure and growing Member State budget deficits, European governments have started to look for new pricing system modalities for the retail market.
Today, tendering or tender-like systems are used in the retail market in a small number of European countries, as it is possible to observe below. Tendering or tender-like systems may be present in countries where dynamic pricing systems or regulated pricing systems are also present.

Despite the efforts of the EGA and National Generic Medicines Associations, payors continue to believe that tendering or tender-like systems are sustainable pricing systems that deliver continued savings and lower prices.

In countries where tendering or tender-like systems exist, there is a reduction of competition as the number of suppliers starts to decrease. Furthermore, originator companies may look to strike early deals with payors to guarantee continued market dominance.

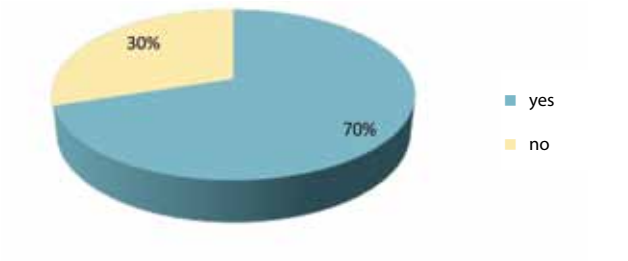
Over time, this reduces competition and the number of suppliers in the market. As a consequence, savings to the healthcare and patient access to affordable medicines will no longer be available. However this is only a small part of the negative impact that tendering

or tender like systems may have on the market, generic medicines companies, patients and governments.

In this chapter, we will look at tendering or tender-like systems in the retail market as well as the impact on the market dynamics and on the stakeholders.

As the following chart 2.1 shows, a large majority of 70% of European Union Member States have discussed the possibility of implementing a tendering or tender-like system in their countries.

2.1 Discussion about Tendering or Tender-like Systems

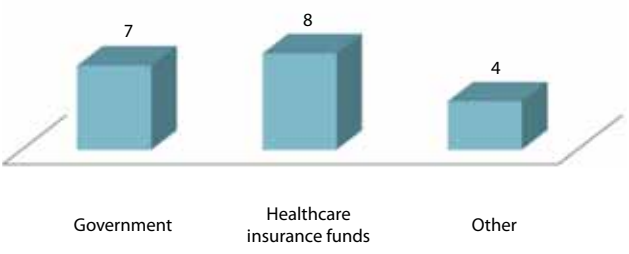


Yes	AT	BE	BG	CZ	DK	FN	FR
	DE	HU	IT	NL	PT	SE	UK
No	HR	LV	NO	PL	ES	TR	

A tendering or tender-like system may involve different actors such as government and health insurance funds.

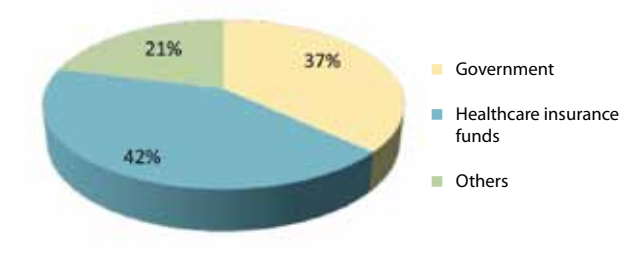
As illustrated in the following charts 2.2 & 2.3, in most of the countries studied, the driving forces for tendering or tender-like systems come from health insurance funds.

2.2 Driving Forces of the Tendering Systems



The following chart 2.3 highlights that for 42% of the countries surveyed healthcare insurance funds are the key driving force in the tendering or tender-like system. They are closely followed by government, which is actively involved in this process for 37% of the countries reviewed.

2.3 Weight of the Driving Forces for the Tendering Systems

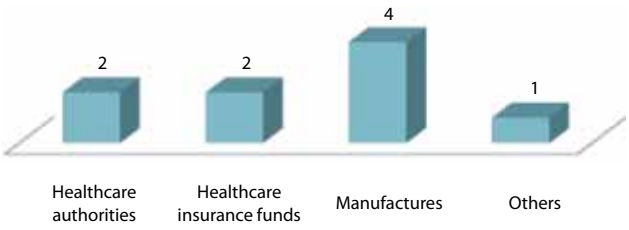


Although a tendering or tender-like system has been discussed in some countries, they have not yet been implemented everywhere. Out of the 14 countries that have an ongoing discussion as to whether to implement a tendering or tender-like system, only 4 of them already have such a system in place. These are: Bulgaria, Germany, Denmark and the Netherlands.
Several bodies may be involved in establishing and operating the tendering or tender-like system including healthcare authorities, healthcare insurance funds and manufacturers. The combination of these different actors may differ from one country to another.

The following graph 2.4 shows that in tendering or tender-like systems, the main actors are:

- Healthcare Authorities
- Healthcare Insurance Funds
- Manufacturers
- Others

2.4 Involved Bodies in the Tendering or Tender-like System

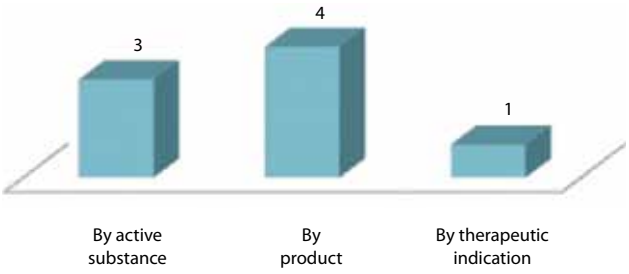


Concerning price negotiations, three options are mostly used:

- by active substance;
- by product; or
- by therapeutic indication

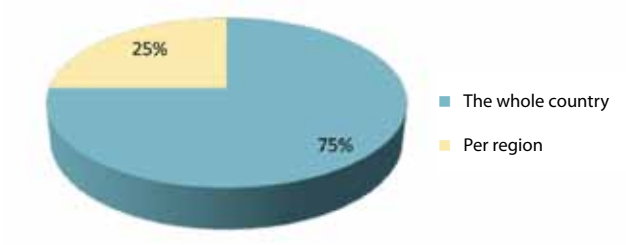
In most of the analysed cases, prices are negotiated by product, followed closely by negotiations by active substance.

2.5 Prices Negociated



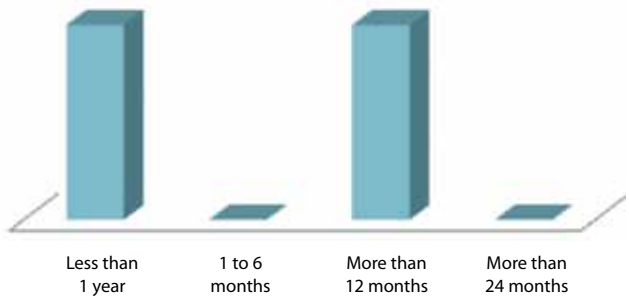
Out of the 4 countries revised for this question, 3 of them award tenders for the whole country (Bulgaria, Hungary, and Netherlands). In the case of Germany, the tender is awarded per region.

2.6 Tender Award



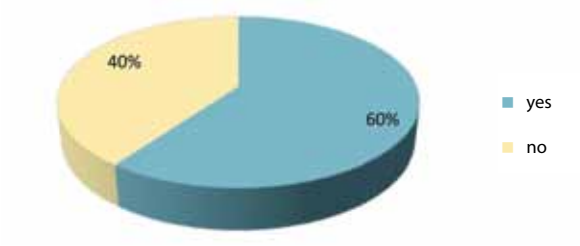
The contractual duration for tenders are equally divided between those that last for less than a year and those that last for over 12 months.

2.7 Contractual Duration of the Tender



In 60% of the analysed tendering systems, the system allows for more than one winner. This is the case in Denmark, Germany and Hungary. After granting the tender, prices may be adjusted in Denmark and in the Netherlands. In addition, in the cases studied, the winner of the tender does not achieve a guaranteed volume as a result of the win.

2.8 More than 1 Winner?



Yes	DK	DE	HU
No	BG	NL	

KEY POINTS

- 70% of the countries reviewed have been through discussions about implementing a tendering system
- The driving forces for tendering systems mostly come from health insurance funds and governments
- In 42% of the European countries surveyed, healthcare insurance funds are the driving force for tendering or tender-like system processes
- In 37% of the European countries analysed, the government is the driving force behind the tendering or tender-like system process
- Concerning price negotiation, three options are possible: by active substance, by product or by therapeutic indication
- In 60% of the analysed tendering systems, the system allows for more than one winner

3 REIMBURSEMENT SYSTEMS

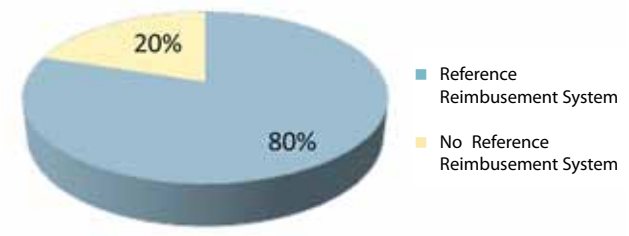
Another tool used by European countries to control health expenditure and to increase patients' market access is the mechanism for the reimbursement of medicines.

Where a reimbursement system is already in place, European governments may use a reference pricing system that will place a ceiling on the reimbursement price. This permits governments to control their health expenditure by only paying up to a maximum level.

The reimbursement limit set by governments or responsible authorities also shapes the final price of a medicine, and the difference between the reimbursement price and the final public price is paid by the patient – the so called patient co-payment. In this chapter we learn about reimbursement systems and how they operate.

Out of the 20 countries surveyed, the majority (80%) have a reference reimbursement system.

3.1 Reimbusement Systems

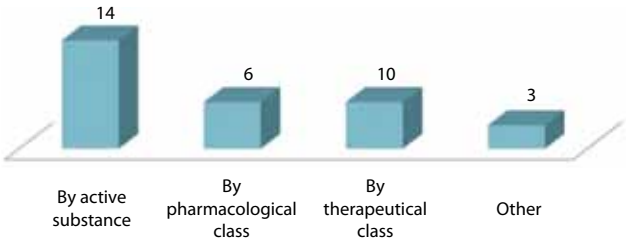


Reference Reimbursement System	AT DE ES	BE HU TR	BG IT	HR LV	CZ NL	FN PL	FR PT
No Reference Reimbursement System	DK	NO	SE	UK			

Within the reference pricing system, the price is established either by:

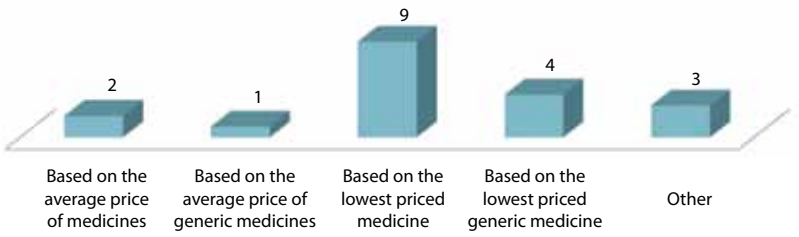
- active substance;
- pharmacological class; or
- therapeutic class

3.2 Reference Price Establishment



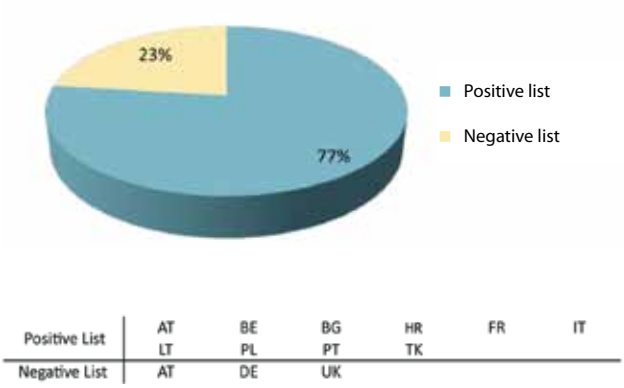
The method of setting the reference price may differ from country to country. As the graph 3.3 illustrates, the vast majority of countries will base their generic medicines prices on the lowest priced medicine. This is the case for Bulgaria, Czech Republic, Finland, Hungary, Italy, Latvia, Poland, Spain and Turkey. Countries can use a different combination of these options in order to set up their reference price. Indeed, they can apply one or more of these systems.

3.3 Setting of the Reference Price



In most cases, there are different reimbursement categories for medicines. Out of the 16 countries analysed, 14 have different reimbursement systems in place.
Some of the countries have a positive list in place, whereas others employ a negative list in their reimbursement system. The following graph 3.4 shows the weight of these two types of lists. Austria has both a positive and a negative list.

3.4 Positive vs. Negative List



KEY POINTS

- 47% of the surveyed European countries base their reference price on the lowest priced medicines
- Within the reference pricing system, the price is established either by: active substance, pharmacological class or therapeutic class
- 77% of the surveyed countries have a positive list in place for the reimbursement system
- 23% of the countries surveyed have a negative list.

PATIENT CO-PAYMENT

In countries where the reimbursement of prescription medicines is not under normal circumstances covered 100%, there is a co-payment allocated to that medicine, and paid by the patient.

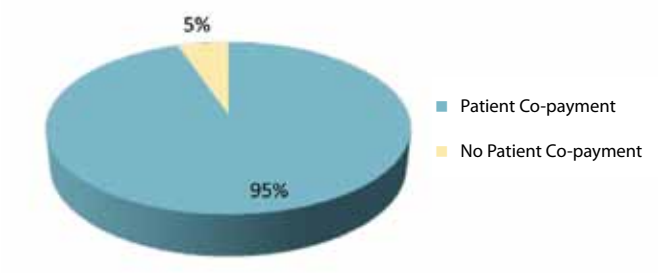
The co-payment is the difference between the final public price and the reimbursement price.

This mechanism is extremely important and used by governments in the promotion of generic medicines, as higher co-payments influence the patient's decision whether or not to accept a generic medicine prescription or a dispensation.

In this chapter the reader can learn about the patient co-payment system for generic medicines in the countries analysed.

The following chart 4.1 reveals that 95% of the analysed countries have a patient co-payment system in place.

4.1 Patient Co-Payment



KEY POINTS

- 95% of the analysed countries have a patient co-payment system in place.
- The two most widespread mechanisms for patient co-payment are % of cost of medicines and difference above referenced price
- 87% of the revised countries do not differentiate between originator and generic medicines within the framework of the co-payment system

The table below displays whether a country does or does not have a patient co-payment system in place.

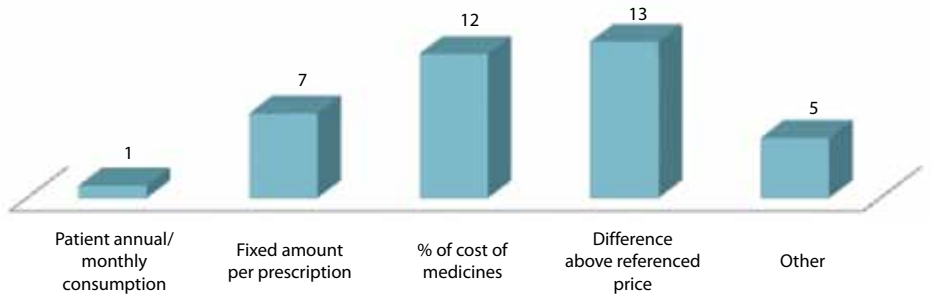
Yes	BE	BG	HR	CZ	DK	FN	FR
	DE	HU	IT	LV	NL	NO	PL
	PT	ES	SE	TK	UK		
No	AT						

Within patient co-payment systems, the mechanism may differ depending on the country.
It may be based either on:

- patient annual/monthly consumption (of medicines);
- fixed amount per prescription;
- % of cost of medicines; or
- difference above referenced price

The following graph 4.2 shows that the two most widespread mechanisms used to determine the level of patient co-payment are % of cost of the medicine and difference above referenced price. Countries may employ different combinations to determine the level of patient co-payment depending on the system in place.

4.2 Patient Co-Payment Bases



PATIENT USE OF GENERIC MEDICINES

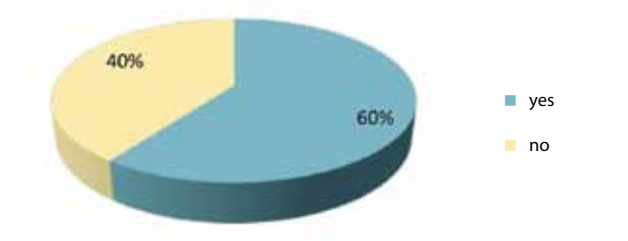
Although patients have a limited contribution with regard to the decision concerning which medicine they will get –this decision is made by the physician or the pharmacist –it is still extremely important to inform patients about generic medicines and incentivise them to request these products.

The patient has the option of accepting or refusing the medicine that is being dispensed; therefore it is important that at that moment in time his decision is made in the most cost-effective way. This can be done by informing patients about generic medicines, educating them and incentivising them with different mechanisms.

In this chapter, we look at the general public's perception and attitude towards generic medicines. This chapter will inform the reader that awareness and perceptions of generic medicines may differ across the countries surveyed.

In order to aid in the understanding of the general public's perception towards generic medicines, the following chart 5.1 displays the countries that carried out consumer studies on the use of generic medicines. Of the 20 countries surveyed, 12 of them handle this type of research.

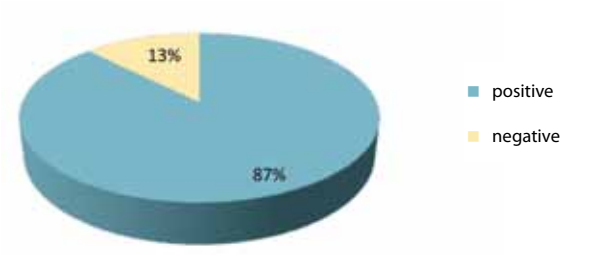
5.1 Studies on Consumer Attitudes towards the use of Generic Medicines



Yes	BE	CZ	FN	FR	IT	NL	NO
	PL	PT	ES	SE	TK		
No	AT	BG	HR	DK	DE	HU	LV

The following chart 5.2 shows that the majority of the 16 countries surveyed have a positive attitude towards generic medicines particularly where the perception of the general public is concerned. Only 2 countries, which represent 13% of the total, do not have a positive perception of generic medicines.

5.2 General Attitude towards Generic Medicines



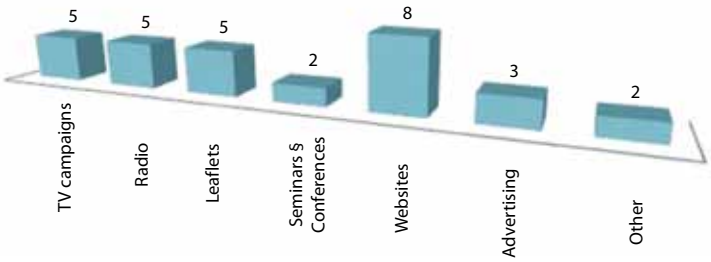
Positive	BE	HR	DK	FN	FR	DE	HU
	LV	NO	PL	PT	ES	SE	TR
Negative	AT	BG					

When considering information campaigns targeting patients in order to inform them about generic medicines, different channels of information were taken into account, such as:

- TV campaigns
- Radio
- Leaflets
- Seminars and Conferences
- Websites
- Advertising

It appears that the most common way to communicate information about generic medicines is through websites. This is followed by TV campaigns, radio and leaflets in equal proportions. The following chart 5.3 shows the different ways used by the countries analysed to raise awareness about generic medicines.

5.3 Information Campaign on Generic Medicines



TV campaingns	HR	CZ	IT	PT	ES
Radio	HR	CZ	LV	PT	ES
Leaflets	AT	HR	FR	DE	ES
Seminars & Conferences	HR	LV			
Websites	HR	CZ	FN	FR	DE
	IT	PT	ES		
Advertising	HR	CZ	ES		

KEY POINTS

- 60% of the European countries analysed have carried out consumer surveys to ascertain the general opinion of patients with regard to generic medicines
- In 87% of the European countries reviewed, the general public have a positive perception of generic medicines
- In 13% of the countries surveyed, patients have a negative opinion about the use of generic medicines
- The most common means of communicating information about generic medicines is through websites

6 GENERIC MEDICINES PRESCRIBING

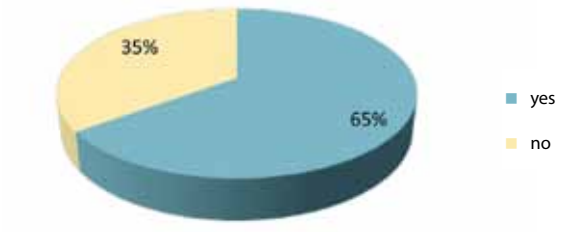
A key role of physicians is to prescribe medicines to patients according to their therapeutic needs. This naturally has financial implications.

Therefore the advantages of generic medicines need to be explained in greater detail to physicians, as part of a physician's training, as is already the case in the UK.

Consequently, national governments develop guidelines to inform and to aid the physician in prescribing. Generic medicines' prescribing is also a concern for governments and national health agencies. In countries where generic medicines substitution is not compulsory, the competent authorities try to provide incentives to physicians to prescribe generic medicines.

Out of the 20 countries asked about this topic, 13 of them stated that some incentives are in place in their country. This proportion represents a majority of 65% of the countries surveyed, as shown in the following chart 6.1.

6.1 Incentives for Doctors to Prescribe Generic Medicines

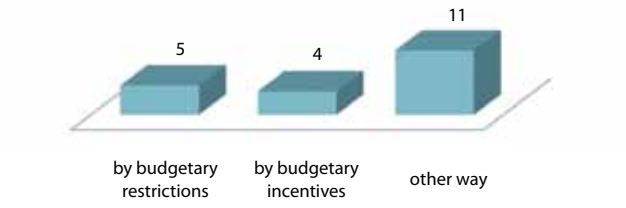


Yes	AT	BE	HR	CZ	FR	DE	HU
	IT	NL	PT	ES	SE	UK	
No	BG	DK	FN	LV	NO	PL	TK

Amongst the European countries reviewed, the methods used to encourage doctors to prescribe generic medicines may differ. This could be achieved either through budgetary restrictions or budgetary incentives. In addition, some countries have national specificities with regard to how they encourage doctors to prescribe generic medicines. For instance, a health insurance fund could use a visit to a doctor as a means of soliciting him to prescribe generic medicines. In some other cases analysed, doctors were required to prescribe lower cost medicines in line with their budgets. There is also evidence of special workforces being paid by the social security services to visit doctors in order to explain their interest in prescribing generic medicines or the cheapest product.

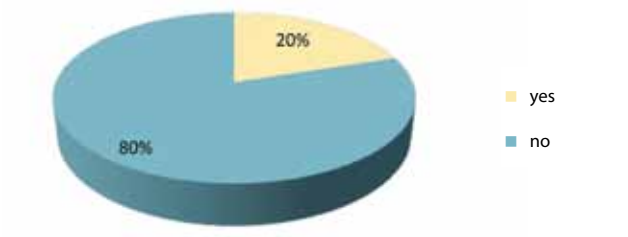
The following chart 6.2 shows that the vast majority of countries surveyed have adopted means other than budgetary restrictions and budgetary incentives (as explained above) in order to encourage doctors to prescribe generic medicines.

6.2 Methods Used to Encourage Doctors to Prescribe Generic Medicines



The large majority of the countries surveyed have no legal requirement to prescribe by INN. Indeed the following graph 6.3 shows that only 20% of the European countries reviewed are obliged to prescribe by INN.

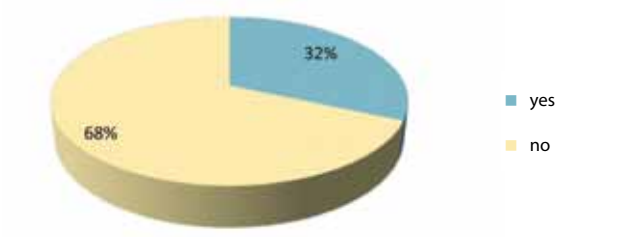
6.3 Legal Requirement to Prescribe by INN



Yes	FR	PT	ES	UK		
	AT	BE	BG	HR	CZ	DK
No	FN	DE	HU	IT	LV	NL
	NO	PL	SE	TR		

The same trend is apparent in terms of encouraging doctors to prescribe by INN, where 32% of countries do so, including Belgium, Denmark, Germany, Netherlands, Portugal, Spain and the United Kingdom.

6.4 Encouragement of Doctors to Prescribe by INN

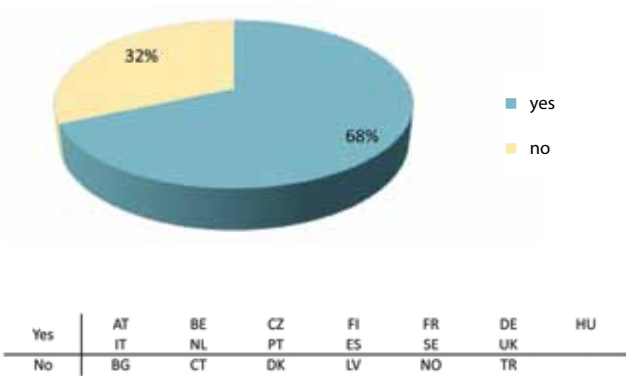


Yes	FR	PT	ES	UK		
	AT	BE	BG	HR	CZ	DK
No	FN	DE	HU	IT	LV	NL
	NO	PL	SE	TR		

In some of the European countries covered, doctors are assisted in generic medicines prescribing.

The following graph 6.5 gives a clear picture of the proportion of countries in which this kind of policy towards generic medicines prescribing is promoted. It appears that in 68% of the countries reviewed, doctors are assisted in prescribing generic medicines.

6.5 Assitance to Doctors in Prescribing Generic Medicines



Yes	AT	BE	CZ	FI	FR	DE	HU
	IT	NL	PT	ES	SE	UK	
No	BG	CT	DK	LV	NO	TR	

KEY POINTS

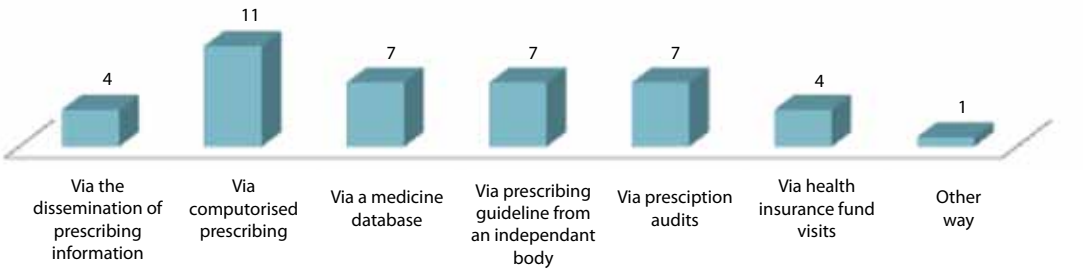
- 65% of the European countries surveyed encourage doctors to prescribe generic medicines
- Doctors can be encouraged to prescribe generic medicines by budgetary restrictions or budgetary incentives. In parallel, some of the countries may have other specific measures to enhance generic medicines prescribing from doctors
- 20% of the revised European countries are legally required to prescribe by INN and 32% are encourage to prescribe by INN
- In 68% of the systems analysed, doctors are assisted in generic medicines prescribing mainly through the use of a computerised database

There are different tools employed to assist doctors in generic medicines prescribing, such as:

- Computerised prescribing
- Medicines database
- Prescribing guidelines from an independent body
- Prescription audit
- Health insurance fund visits

As shown in chart 6.6, it appears that most doctors are assisted by means of computerised prescribing. This is followed in equal proportions by the provision of aid via a medicines database, prescribing guidelines from an independent body and by prescription audits.

6.6 Ways to Assist Doctors in General Medicines Prescribing



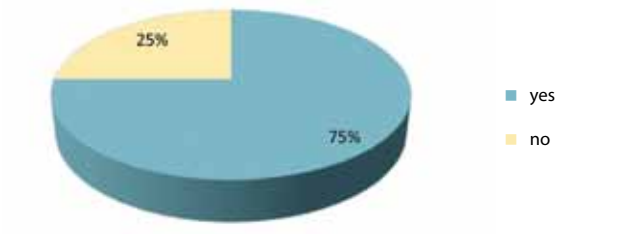
7 GENERIC MEDICINES SUBSTITUTION

Generic medicines dispensing is encouraged as a cost containment strategy for the management of healthcare resources. In this process, substitution by a less expensive generic medicine alternative is made, which results in significant cost savings to state health budgets and a patient's own contribution.

Generic medicines substitution contributes to increased savings and control over healthcare expenditure. If substitution is legally allowed, when a doctor prescribes a medicine and does not prevent generic medicines substitution by any means, the pharmacist should normally substitute the prescribed originator medicine by a generic medicine if one is available.

As the following chart 7.1 shows, in 75% of the countries analysed, substitution is allowed. However, this is not the case for Austria, Belgium, Bulgaria, Croatia and the United Kingdom, where substitution is not allowed.

7.1 Generic Medicines Substitution Allowed



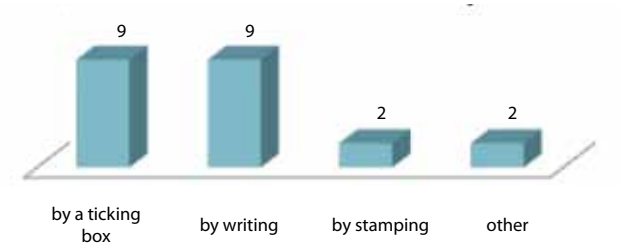
Yes	CZ LV TR	DK NL	FN NO	FR PL	DE PT	HU ES	IT SE
No	AT	BE	BG	HR	UK		

As you can see in chart 7.2, there are different ways used to prevent substitution:

- by a ticking box
- by writing
- by stamping
- other

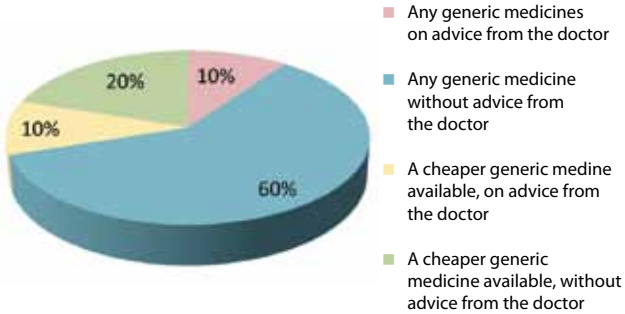
The most predominant method used by the countries surveyed are by a ticking box and by writing.

7.2 Ways Used to Prevent Generic Medicines Substitution



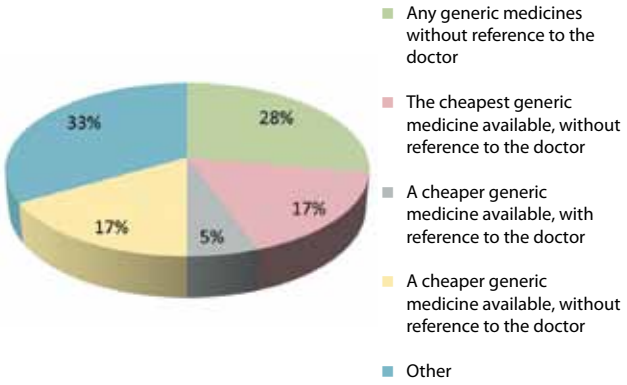
When looking at the three following charts, we can identify the behaviour of the pharmacist each time a substitution occurs. For instance, when a doctor prescribes a branded original product, in 60% of the analysed countries the pharmacist will dispense a generic medicine without advice from the doctor. 20% of the time, the pharmacist will dispense a cheaper generic medicine, on the advice of the doctor. Those figures are presented in the following graph 7.3.

7.3 Pharmacists' Dispensing Habits When a Doctor Prescribes a Branded Original Product



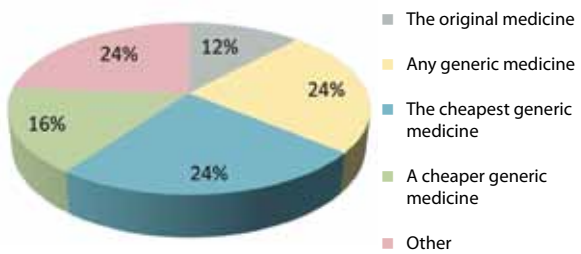
In the same way, when doctors prescribe branded generic medicines, in 28% of the cases, the pharmacist will tend to dispense any generic medicine, without reference to the doctor. Pharmacists' response to substitution may also depend on the availability of the drug prescribed or the patient's request.

7.4 Pharmacists' Dispensing Habits When a Doctor Prescribes a Branded Generic Medicine



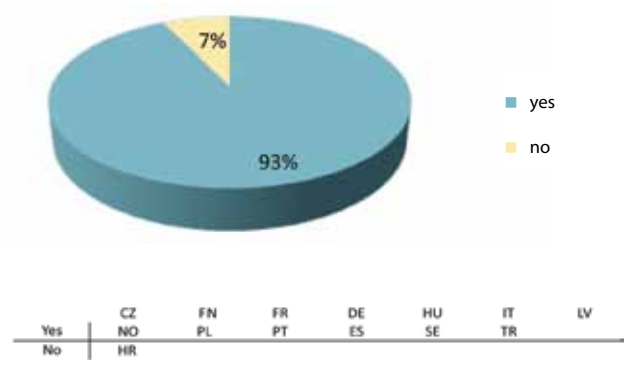
Finally, when a doctor prescribes a medicine using INN, the pharmacist will in 24% of the cases surveyed, prescribe either any generic medicine, or the cheapest generic medicine.
This is represented in the following graph 7.5. As explained previously, pharmacists' dispensing habits may also depend on the availability of the drug prescribed as well as the patient's request with regard to co-payment and reimbursement

7.5 Pharmacists' Dispensing Habits When a Doctor Prescribes a Medicine Using INN



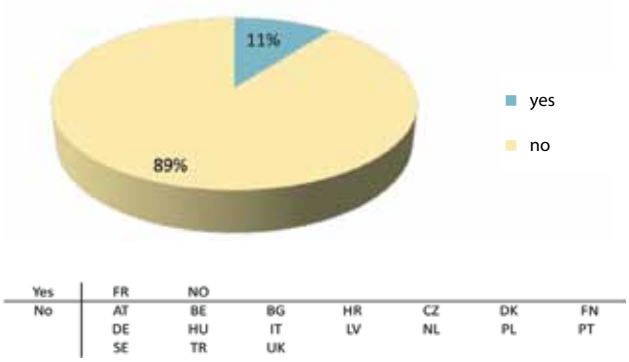
As far as the role of patients in the substitution process is concerned, it is necessary to inform them in a number of the European countries analysed. It can be observed that in 93% there is an obligation to inform the patient of substitution.

7.6 Obligation to Inform Patient of Substitution



The following chart 7.8 shows that only 11% of the countries surveyed have in place measures to reward generic medicines dispensing. Therefore the large majority of 89% does not reward pharmacists when they dispense generic medicines to patients.

7.8 Reward for Pharmacists When They Prescribe Generic Medicines

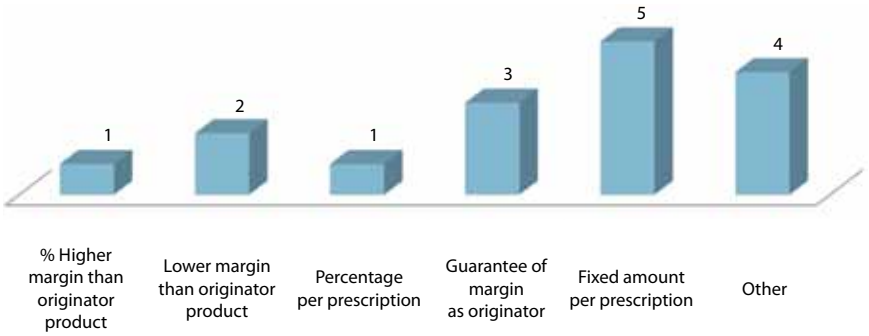


The way pharmacists are remunerated may differ from one country to another. Several options are in place, such as:

- Higher margin than originator product
- Lower margin than originator product
- Percentage per prescription
- Guarantee of margin as originator
- Fixed amount per prescription

The following chart 7.7 shows that in most countries surveyed pharmacists are remunerated via a fixed amount per prescription (31%).

7.7 Pharmacists Remuneration



KEY POINTS

- In 75% of the countries analysed, substitution is allowed
- Generic medicines substitution is compulsory in 40% of the countries analysed
- Pharmacists' response to substitution:
  - when a doctor prescribes a branded original product, in 60% of the countries analysed, the pharmacist will dispense a generic medicine without advice from a doctor
  - when a doctor prescribes a medicine using the INN, the pharmacist will in 24% of the cases reviewed prescribe either any generic medicine, or the cheapest generic medicine
  - when doctors prescribe branded generic medicines, in 28% of cases the pharmacist will dispense any generic medicine, without reference to a doctor
- In 93% of the countries surveyed, the patient has to be informed about substitution
- 31% of pharmacists are remunerated with a fixed amount per prescription
- The large majority of 89% get no reward for prescribing generic medicines

GENERIC MEDICINES DISTRIBUTION

Pharmaceutical markets are constantly changing as a result of regulations imposed by governments and responsible authorities, as well as market dynamics.

All this has a major influence on the way that generic medicines behave in the market. For this reason we have added this new chapter in order to offer a response to the increasing number of questions asked by EGA members.

This chapter will try to shed light on the mechanism governing the distribution of medicines from the manufacturer to the wholesaler and on to the pharmacist. It will explain the dynamics that are born of the relationship between the stakeholders.

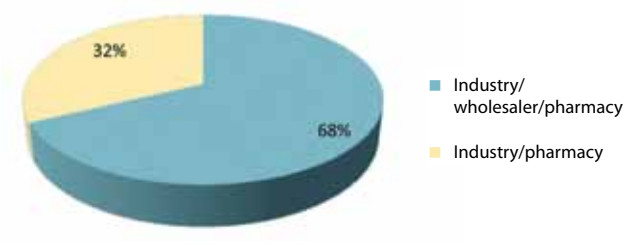
Key information that can be found in this chapter ranges from the way medicines are distributed in the market to what the wholesalers' and pharmacists' margins are, and on to discount levels regulated by law.

In order to learn more about the distribution schemes, the reader can first observe that there are two possible routes:

- Industry/ wholesaler/ pharmacy
- Industry/pharmacy

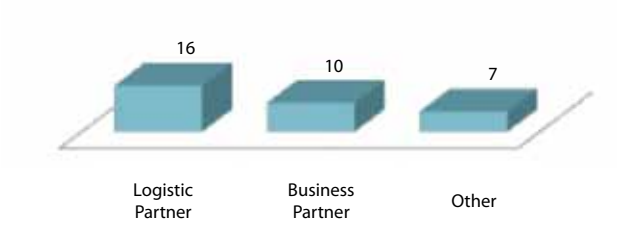
The following chart 8.1 shows that in 68% of the countries reviewed, the distribution of generic medicines goes through industry/ wholesaler/ pharmacy.

8.1 Distribution of Generic Medicines

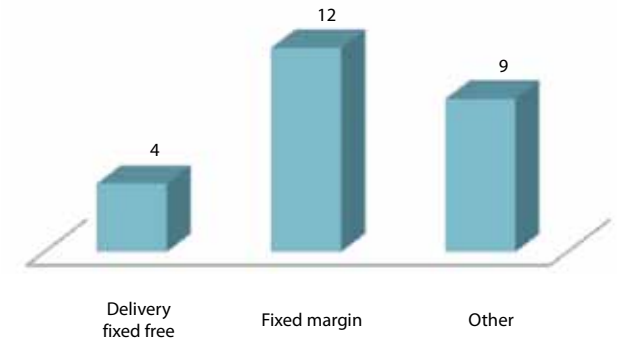


Industry/wholesaler/pharmacy	AT	BE	BG	HR	CZ	DK
	FN	FR	DE	HU	IT	LV
	NL	NO	PL	PT	ES	TR
	UK					
Industry/ pharmacy	BE	BG	CT	FR	DE	IT
	LV	PT	UK			

The role of the wholesaler may differ from one country to another within the generic medicines distribution system. As the following chart 8.2 shows, in almost 50% of cases, the wholesaler will play the role of a logistical partner.



8.2 Role of Wholesalers



Pharmacies' profits may be based on:

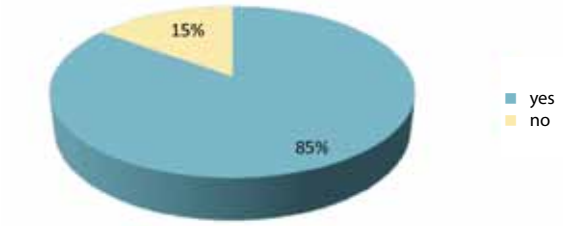
- Delivery, fixed fee
- Fixed margin
- Other

According to the following chart 8.3, in 48% of the countries surveyed, pharmacists' profits are based on a fixed margin.

8.3 Basis of Pharmacies Profit

Finally, the reader may observe, discounts/rebates are legally permitted in 85% of the countries analysed. This leads to the conclusion that such practices are not legal in the remaining 15% of the countries surveyed, amongst them Bulgaria, Finland, and Norway.

8.4 Grant of Discounts and Rebates



Yes	AT	BE	HR	CZ	DK	FR
	DE	HU	IT	LV	NL	PL
	PT	ES	SE	TR	UK	
No	BG	FN	NO			

KEY POINTS

- In 68% of the countries reviewed, the distribution of generic medicines goes through industry/ wholesaler/ pharmacy
- In almost 50% of cases, the wholesaler is considered as a logistical partner in the generic medicines distribution chain; in the other 30% of cases, the wholesaler may be viewed as a business partner and in the remaining 20% of cases the countries under review have their own peculiarities with regard to the role of the wholesaler
- In 48% of the countries surveyed, pharmacists' profits are based on a fixed margin
- Discounts/rebates are legally allowed in 85% of the countries reviewed

9 MARKETING AUTHORISATION

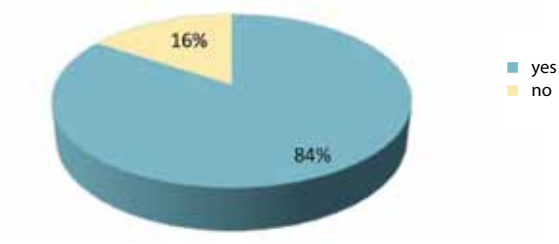
One of the main hurdles that generic companies must overcome is difficult market access. In the vast majority of countries it is a time-consuming and expensive process.

The following pages will highlight the main aspects that impact the access of generic medicines to the markets. The main topics covered in this report are:

- Marketing authorisation and price and reimbursement applications
- Time delay for a generic medicine to receive its price and reimbursement approval
- Granting of a generic medicines Marketing Authorisation in the context of SPC periods
- Conditions for obtaining a substitution/ interchangeability status (bioequivalence, SmPC, salt/isomer/ester).

The following chart shows that in 84% of the European countries surveyed, the grant of a marketing authorisation is necessary in order for an application to be made for a generic medicine price.

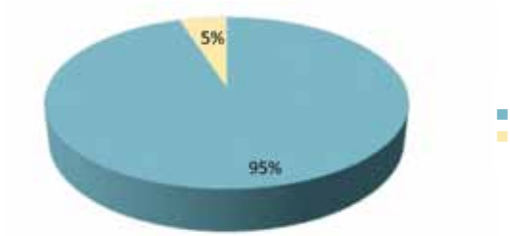
9.1 Necessity of Having a MA to Apply for Generic Medicines Price



Yes	AT	BE	BG	HR	CZ	DK	FN
	FR	HU	IT	LV	NO	PL	PT
	ES	SE					
No	DE	TR	UK				

In the same way, 95% of the countries analysed require a marketing authorisation in order for an application for generic medicines reimbursement to be made.

9.2 Necessity of Having a MA to Apply for Generic Medicines Reimbursement



Yes	AT	BE	BG	HR	CZ	DK	FN
	FR	DE	HU	IT	LV	NE	NO
	PL	PT	ES	SE	TR		
No	UK						

Regarding the impact of the legal basis for a marketing authorisation on pricing and/or reimbursement of generic medicines, it has no impact for 94% of the countries surveyed, the legal basis has no impact on pricing and reimbursement of generic medicines.

9.3 Impact of the Legal Basis on MA pricing and/or Reimbursement of Generic Medicines

Yes	PT							
No	BE	BG	HR	CZ	DK	FN	IT	DE
	LV	NO	PL	ES	SE	TR	UK	

In addition, pricing and reimbursement of medicines can be influenced by the differences in therapeutic indications between the generic medicine and the originator. This is the case for 17% of the countries surveyed, namely Belgium, Italy and Latvia.

9.4 Where a Difference in Therapeutic Indications Between Generic and Originator Medicines Impact on Pricing and/ or Reimbursement

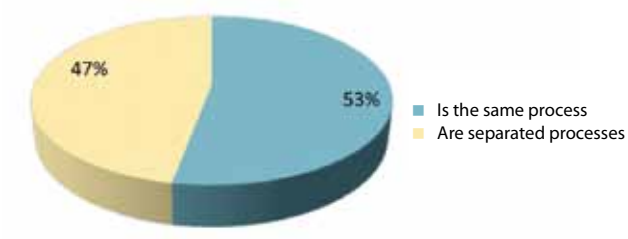
Yes	BE	IT	LV				
No	BG	HR	CZ	DK	FN	FR	DE
	NL	NO	PL	PT	ES	SE	TR
	UK						

Regarding the application for pricing and reimbursement, this can be either:

- The same process
- Separate processes

The following chart 9.5 shows that in 53% of the cases analysed, we can observe that the proportion is almost equal as to whether the application for pricing and reimbursement is the same (53%) or separate (47%) process.

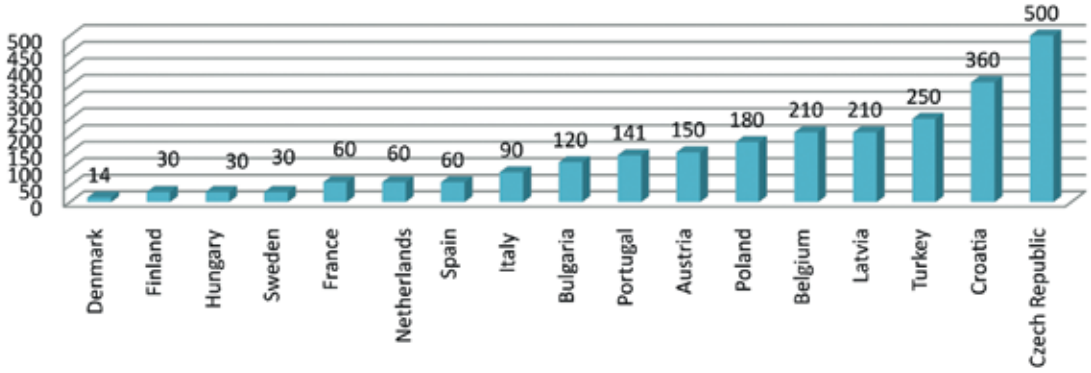
9.5 The Application for Pricing and Reimbursement Process



Is the same process	AT	CZ	DK	FN	FR	HU
	IT	PL	SE			
Are separate process	BE	HR	BG	LV	NO	PT
	ES	TR				

The time required to obtain pricing and reimbursement approval for generic medicines varies amongst the countries revised. As the chart 9.6 illustrates, it ranges from 14 days in Denmark to 500 days in Czech Republic.

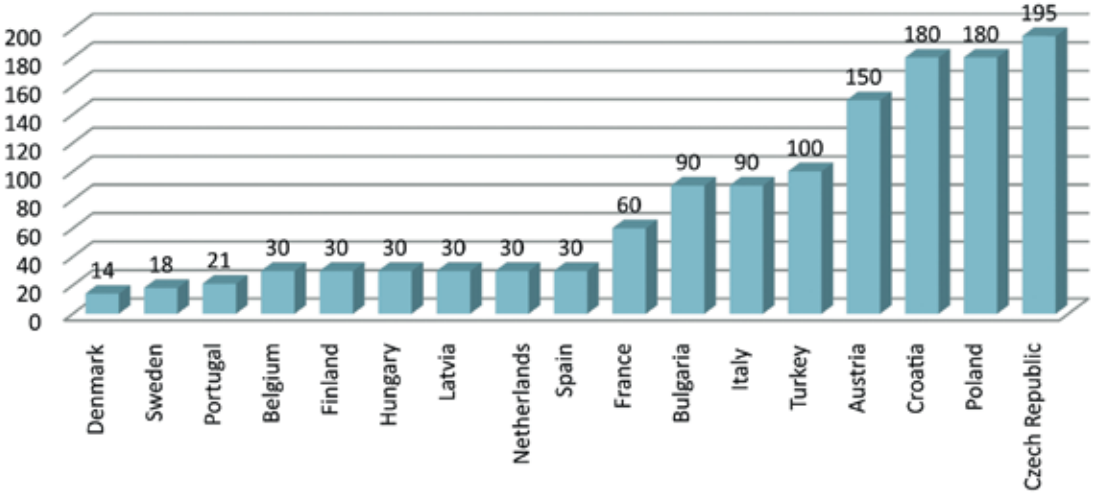
9.6 Average Time for Generic Medicines to Receive Pricing and Reimbursement Approval



The time required to obtain pricing approval for generic medicines differs significantly amongst the countries studied.

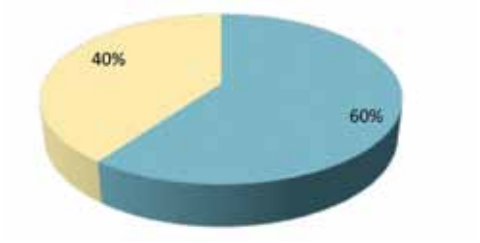
As chart 9.7 shows, it ranges from 14 days in Denmark to 195 (which is an average between 150-240 days) in the Czech Republic.

9.7 Average Time for Generic Medicines to Receive Pricing Approval



These legal timelines are not respected in all countries. Chart 9.8 reveals that the majority (60%) respect the time limits but at the same time this means that a significant minority of 40 % do not.

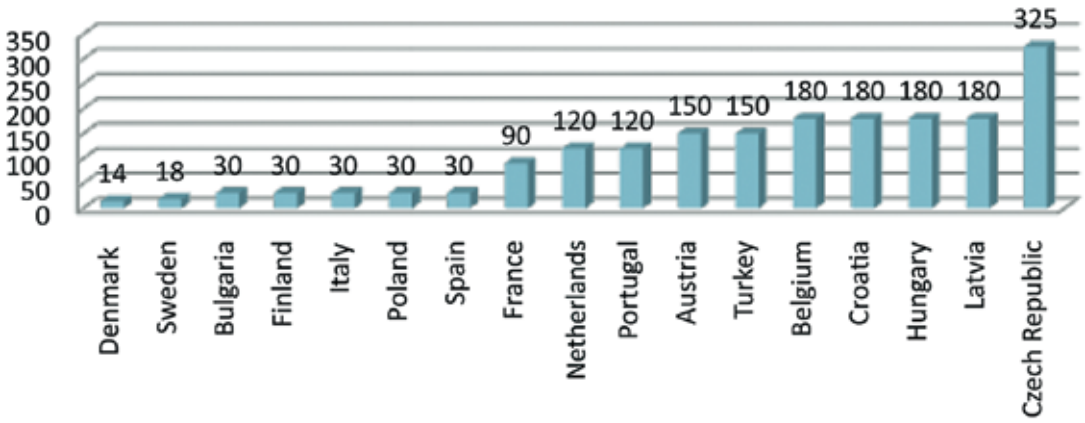
9.8 Respect of Legal Timelines for Pricing Approval



Yes	AT NO	BE PT	BG SE	HR	FN	LV
No	CZ	DE	IT	PL	ES	TR

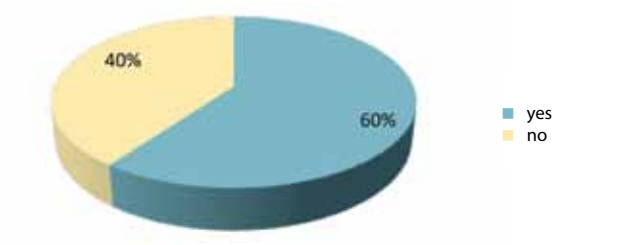
Procedures pertaining to the reimbursement approval for generic medicines also vary from country to country in terms of the average time required. Indeed, as the following graph, 9.8, illustrates, it can take from 14 days in Latvia to 325 days (average of 150-500 days) in Czech Republic.

9.9 Average Time for Generic Medicines to Receive Reimbursement Approval



The legal timelines for reimbursement approval indicated above are not always respected. However, the following graph shows that they are respected in the majority of the countries surveyed (60%).

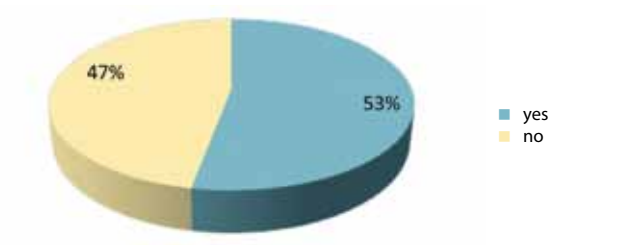
9.10 Respect for Legal Timelines for Reimbursement Approval



Yes	AT NL	BE NO	BG SE	HR	FN	LV
No	CZ	DE	PL	PT	ES	TR

As the next chart, 9.11, illustrates, the granting of a generic medicine market authorisation and price during the patent/SPC period is allowed in 53% of the countries surveyed. Thus the reader can observe that it is almost proportional with those countries in which it is not allowed.

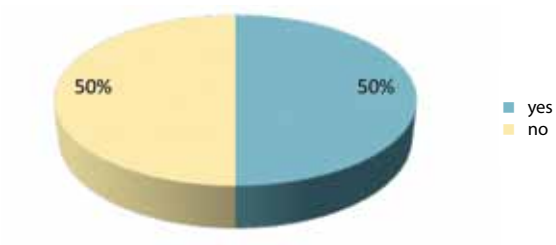
9.11 Granting of Price Status for Generic Medicines during the patent, SPC period



Yes	BE PT	FN SE	FR TR	IT	NO	PL
No	AT LV	BG ES	HR	CZ	DE	HU

With regard to the granting of reimbursement for a generic medicine during the patent/ SPC period, this is permitted and forbidden in an equal proportion of the countries under review, as illustrated in the following graph, 9.12.

9.12 Granting of Reimbursement Status for Generic Medicines during the patent, SPC period



Yes	AT PL	BE PT	FN SE	FR	IT	NO
No	BG NL	HR ES	CZ TR	DE	HU	LV

KEY POINTS

- 53% of European countries have the same process for pricing and reimbursement of generic medicines
- 47% of the European countries analysed have separate processes for pricing and reimbursement of generic medicines
- The legal timelines for generic medicines pricing approval are respected in 60% of the covered countries
- The legal timelines for reimbursement approval are respected in 60% of the countries covered
- In 53% of the countries surveyed, it is permissible to have a generic medicine price granted during the patent/SPC period
- 50% of the countries under review allow the granting of reimbursement status for generic medicines during the patent/ SPC period

GENERAL INFORMATION ABOUT GENERIC MEDICINES

One of the main hurdles that generic companies must overcome is difficult market access. In the vast majority of countries it is a time-consuming and expensive process.

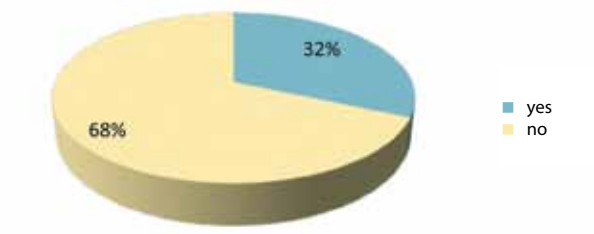
In recent years there has been an increasing need to show how the European generic medicines industry is a major contributor to the sustainability not only of the healthcare sector, but also to the economy and employment. With this in mind, the EGA is making available this publication, which offers concrete information on the extent to which the European generic medicines industry makes this contribution.

It is also important to stress that only 20 countries were surveyed during the compilation process and therefore only a limited picture or conclusion can be drawn from the information contained in the tables. However, as stated in the recent IMS report[3], the European generic medicines industry is responsible for thousands of millions of Euros in savings for the European healthcare system, as well as for creating employment and contributing to the buoyancy of the European economy.

[3] IMS. INTELLIGENCE. APPLIED. Alan SHEPPARD, Generic Medicines: Essential contributors to the long-term health of society, SECTOR SUSTAINABILITY CHALLENGES IN EUROPE

As the reader may observe, governments from 68% of the countries surveyed implemented measures to stimulate the prescribing and dispensing of generic medicines in 2010.

10.1 Implementation of Government Measures to Stimulate the Prescribing and Dispensing of Generic Medicines in 20



Yes	CT	HU	IT	NL	PT	ES
	AT	BE	BG	CZ	DK	FI
No	FR	DE	NO	PL	SE	TR
	UK					

10.2 General Figures about Generic Medicines

The two following tables sourced from The Market Review, Part 1, show how promising the generic medicines industry is in the European societal perspective.

This can be observed in terms of the number of people employed either directly or indirectly by generic medicines companies, the annual savings thanks to the use of generic medicines and the total investment in research & development in generic medicines.

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Number	Total N/A	Total
What is the number people employed by generic medicines companies in 2010?	550	600	10000	650	5500	-	-	2000	-	-	5000	-	800[1]	300[2]	25000	1890	-	200	15000	3000	70490	6	20
What is the number of people indirectly employed by generic medicines companies in 2010?	-	1500	-	-	-	-	-	10000	-	-	6000	-	-	-	20000	-	-	-	-	-	37500	16	20

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Number	Total N/A	Total
What annual savings are realised through the use of generic medicines in 2010?	0.10 BN	-	-	-	-	1.10 BN	-	1.70 BN	10.10 BN	-	0.3 BN	-	1.30 BN	-	0.70 BN	-	-	0.56 BN	0.37 BN	9.82 BN	26 BN	10	20
What is the total investment in R&D of generic medicines in 2010?	-	-	-	-	2M	-	-	-	-	-	15.30 M	-	-	-	-	-	-	-	-	-	17.30 M	18	20