

2
Sector
barometer

9
Study :
European pharma-
ceutical companies:
is austerity fatal?

+
Has the pharmaceutical
sector suffered from
the economic crises?

9
+ New shocks
to absorb
Why is austerity
not fatal

11

13

PANORAMA SECTORS

THE COFACE ECONOMIC PUBLICATIONS

November 2014

By Coface Group Economists



T This end of year panorama starts with the risk assessment of 14 sectors in the three regions we monitor. North America is witnessing major evolutions. Our assessments in this region are improving for chemicals, transportation and textile-clothing. These three sectors are benefiting from the good shape of the American economy and from the fall in oil prices. This drop is particularly helping US airline companies, who are reaping the fruits of their efforts to restructure their activities and

improve their margins. North American chemical companies are gaining advantages through their access to non-conventional oil and gas, and through the upward trend in the activities of their main customers (automotive, construction). Lastly, the textile-clothing sector is being strengthened by the dynamics in employment and household consumption. The sudden drop in oil prices constitutes one of the major changes since our last publication. This will give a boost to sectors such as chemicals, but will have a negative effect for oil producers and contractors.

The following study focuses on the pharmaceuticals sector in Western Europe, which is experiencing a constraint in drug sales. Pharmaceutical companies have many hurdles to overcome, such as the restrictions in health spending, mainly due to the economic crisis, and state regulation of their activities. One question remains: is austerity lethal for this sector? We will see that this sector can grasp growth from the emerging countries, as well as growth generated by innovation in complex therapeutic areas such as oncology, diabetes and cardiovascular illnesses.

ALL THE OTHER GROUP PANORAMAS ARE AVAILABLE ON
<http://www.coface.com/News-Publications/Publications>

coface
FOR SAFER TRADE

NOVEMBER 2014

SECTOR BAROMETER

BY OUR ECONOMISTS



Khalid AIT YAHIA
Economist



Guillaume BAQUE
Economist

« Coface is upgrading its risk assessments for the chemicals, transportation and textile-clothing sectors in North America »

Coface is upgrading its risk assessments for the chemicals, transportation and textile-clothing sectors in North America. Apart from the still favourable growth prospects in the United States, these sectors benefit from the marked decline in the prices of raw materials. From a European perspective, the

weak recovery requires Coface to keep its sector risk assessments unchanged for this region. And, in emerging Asia, the sectors linked to infrastructure in China are continuing to suffer from overcapacity (metallurgy, chemicals and construction). Against this, the automotive, distribution and services

sectors are still benefiting from the rise of the middle class and increased household consumption. You will find below a table summarising Coface's sector risk assessments, followed by a detailed analysis of 6 sectors.

SECTORIAL RISK ASSESSMENT			
Sectors	Western Europe *	Emerging Asia	North America
Agro-food	●	●	●
Automotives	●	●	●
Chemicals	●	●	● ↗
Construction	●	●	●
Electronics, IT **	●	●	●
Energy	●	●	●
Engineering	●	●	●
Metals	●	●	●
Paper-Wood	●	●	●
Pharmaceuticals	●	●	●
Retail	●	●	●
Services	●	●	●
Textile-clothing	●	●	● ↗
Transportation	●	●	● ↗

Sources : Datastream, Coface

● Moderate risk ● Medium risk ● High risk ● Very high risk

* See credit risk chart page 8

** Electronics, information technology and telecoms

1 CHEMICALS

Sector trends are mixed, depending on regions. North America is performing well and, moreover, has become the preferred country for many players in the sector. As for Western Europe, it is still stuck in a sluggish recovery, which is weakening the sector. However, the fall in crude oil prices, if it lasts, will act as a stimulus by slightly lowering production costs. Finally, the sectors' players in emerging Asia remain weak, although some are looking beyond their own frontiers in order to capture value.

North America

Industrial production in the United States grew 3.2% at the end of Q3 2014, compared with the same period in 2013. Sales of automotives are also doing well (up by 1.4% over the first ten months of the year, compared with 2013), in a context of sustained household consumption. As for construction, activity and prices are rising, but they

remain below pre-crisis levels in a context of slightly lower public investment and relatively high household debt.

We are reassessing the North American chemicals sector to moderate risk, as it is fully benefiting from the competitiveness gains due to lower production costs and because its customers are benefiting from the healthy economic situation.

Western Europe

Manufacturing activity in the Eurozone has not succeeded in recovering, posting a fall of -1.9% over one year in August 2014. Industrial activity remains at half-mast in Italy and France. It also slowed this summer in Germany (-4.3%) due to the Russian-Ukrainian crisis and temporary seasonal factors. However, although these elements do not look very promising, the fall in oil prices gives a boost to companies in the chemicals sector, as naphtha prices are also down – something that will reduce the competitiveness gap with North American rivals.

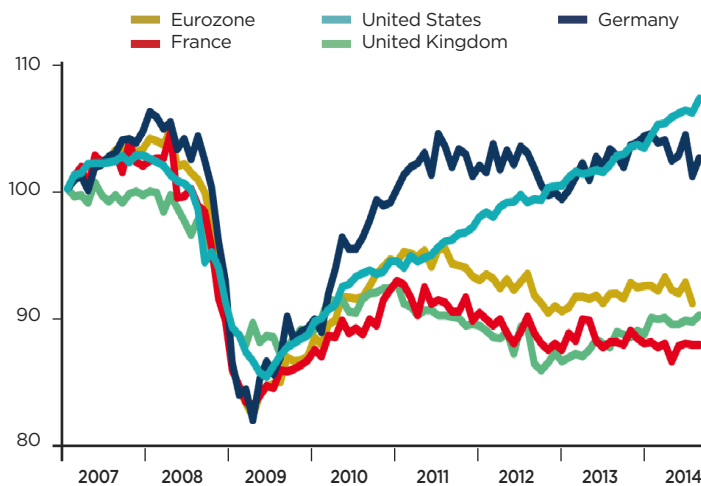
The level of risk remains high.

Emerging Asia

Manufacturing activity will benefit from the slight acceleration in world growth this year, though the summer's disappointments from Europe are hitting the most exposed economies in the region, (such as Korea where business confidence was down for the second consecutive month in October 2014). However, the signs from India are positive. Manufacturing activity is still in the region of expansion, above the mean (51.6). Finally, the sector's prospects are still mixed in China, where some segments such as PVC (which has been badly affected by a slowdown in construction), are increasing their share for export.

We are keeping the risk level as high for this region.

Industrial production (index, 100 = Jan 2007)



Source : National statistics institutes

2 ELECTRONICS, IT

World smartphone sales remain strong thanks to the emerging countries. Sales of tablets are growing more slowly than in 2013, while computer sales continue to fall - though less sharply than in previous years. The software industry is reporting a growth in financial results, particularly in the United States. According to IDC, software sales are expected to rise by 6% compared with 2013.

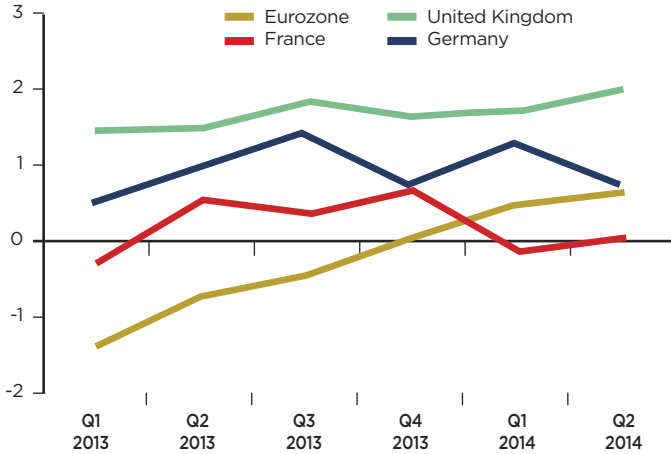
North America

Tablet sales are sharply up (+18% at the end of September 2014, over 12 months). This is partly explained by sales to schools and also by the attraction of consumers to low-cost tablets according to IDC. The software industry is recording good results, thanks to the move towards cloud computing. Healthy American growth and

falling unemployment, together with updated products, are further explanations for this growth. However, this economic dynamism is not positively impacting American wages.

We are not changing our assessment of the risk, which is medium.

Private consumption
(%, year on year)



Source : National statistics institutes

Emerging Asia

Smartphone sales were up by 25% year-on-year at the end of September 2014. Chinese and Indian manufacturers are developing the low-cost segment, with a good presence in the rest of South East Asia, as well as in the Middle East and Africa. Computer sales, for their part, are stabilising after falling for several years. The Chinese and Taiwanese groups have managed to keep or even increase their market share, to the detriment of their American competitors. Profitability for the sector as a whole was up 3.9% year-on-year at the end of September 2014.

The risk remains medium.

Western Europe

The situation remains difficult in Western Europe in the face of sluggish demand. Growth and job prospects for France (expected growth +0.4% in 2014 according to Coface) and Italy (-0.2%) are weak, while German growth has been revised downwards. Accordingly the sector's turnover was down 1.8% year-on-year in September 2014.

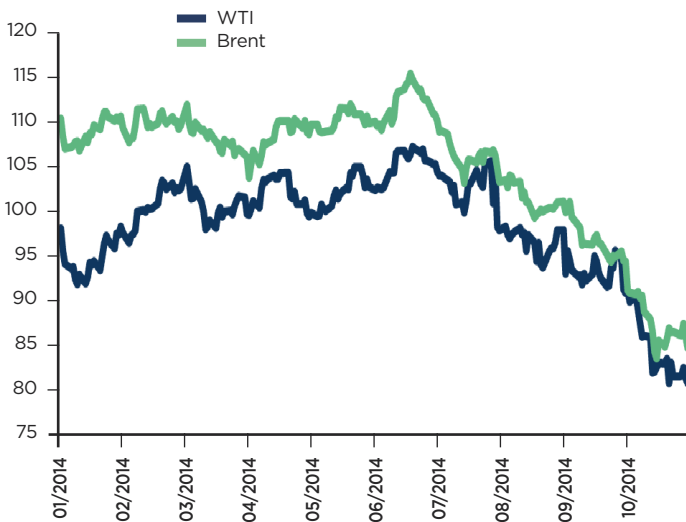
The risk remains high in the short term.

3 ENERGY

Oil prices have fallen in recent weeks. This sudden fall has affected most players in the oil segment and also that of gas, since the price of gas is correlated with that of oil. The risks will become apparent if

prices remain in the region of \$80/barrel, not only weakening the oil-related companies but also reducing investment in unconventional hydrocarbons.

Price of a barrel of oil (USD)



Source : Thomas Reuters

North America

The major oil companies announced the results of their production activity in half tones in Q3 2014. For our part, we observe a 7% fall in profitability year-on-year. The WTI price fell by more than 25%, to \$80 a barrel on 31 October, approaching the break-even level for investments in shale oil. Moreover, because of strong investment in recent years, there has been a strong expansion in contracting parties' supply. Faced with fewer projects in the future, if prices remain low, the oil-related sector will have excess supply.

Prospects will depend on changes in WTI prices, as will our risk assessment, which remains unchanged at the moment.

Western Europe

Following the example of the WTI in the United States, Brent has also fallen since its June peak (-25%), to reach \$85/barrel on 31 October. The big production companies are all recording a fall in profits for Q3 2104. The refining sector, for its part, is facing overcapacity because of stalling demand. Moreover, competition from new players in the sector is further weakening the refiners. Margins are low (+/- €20/tonne) and the sector's players are consequently suffering losses. The fall of Brent, if it lasts, will not be enough to compensate for those fundamentals which have deteriorated.

The level of risk remains medium.

Emerging Asia

The fall in prices has also affected the profits of Asian national companies. However the risk is greatest for the refiners, affected by the reduction in subsidies on diesel (India, Indonesia), as well as by stagnant demand for diesel. Effectively, sluggish demand is leading to falls in production in some countries (South Korea, Japan), in order to preserve refining margins. Exports to Europe are not enough to make up for the domestic market. As such, the Singapore diesel benchmark of 500ppm has fallen by 3% since August.

We are not making any change in our risk assessment.

4 RETAIL

The situation varies greatly between developed and emerging countries. Effectively, the former are suffering from sluggish household consumption. At the same time, lower food prices, linked to good harvests and accentuated by the ban on exporting certain processed food products (from the EU and the United States in particular) are affecting the margins of some retailers, which are undergoing a prolonged slowdown in their sales. To stem this downturn in growth, they are investing in new growth sources, especially in e-commerce. In contrast, the number of emerging middle-class households continues to grow, which is driving distribution growth in emerging Asia.

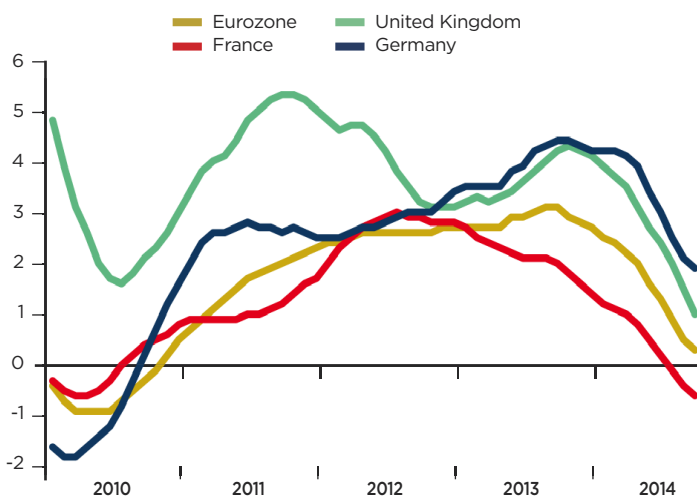
Western Europe

The price war is at its fiercest in large scale distribution. After eight consecutive quarters of decline, household consumption has been growing again in the Eurozone since the third quarter of 2013 (+0.8% year on year in Q2 2014). However, purchasing power remains constrained by weak growth in wages and by unemployment, which still affects 11.5% of the population using the common currency.

In this context, the major food retailers are continuing to drive prices down in order to maintain their business volumes. Accordingly, food prices have been falling in the Eurozone since May 2014 (-0.3% in September 2014 year on year). The same is true in the United Kingdom, where this trend has not been observed since October 2004 (1). Although private consumption continues to grow (+2.0% year on year in Q2 2012) and unemployment continues to improve (6% in July 2014), wages are stagnating. Households are increasingly turning to hard discount retailers, chiefly from Germany, such as Lidl and Aldi. Although still less than the 11.9% observed in France, their market share has grown considerably to reach 8%, compared with 5% in 2012 (Kantar World panel). Tesco, the UK's top supermarket and No3 in the world after Walmart and Carrefour, has seen its market valuation halved since the beginning of the year, linked to internal scandals and three profit warnings in 2014. It is the same story at Sainsbury's, the UK's second leading supermarket, which has revised its annual sales forecasts downwards.

The risk remains medium but a prolonged period of sluggish household consumption could lead to a deterioration.

Food price variations
(Average annual %)



Source : Eurostat

(1) Two consecutive months of decline

Emerging Asia

The region's growth remains dynamic at 6.3% in 2014, identical to 2013 according to Coface. The sector benefits from the rise of the emerging middle classes, who are equipping themselves with durable goods and want to enjoy the same comfort as their western counterparts. The low rate of domestic appliance ownership is an indication of the significant growth potential of these countries. For example, only 15% of the rural population in Vietnam has a washing machine, while half of them have a refrigerator, which in turn increases the propensity to consume fresh products.

In China, the volume of retail sales grew by 11% in 2013, as a result of the continued rise in wages. This rise of the middle class has resulted, in particular, in a rapid increase in the number of physical shops. In 2013, the number of shops increased by 19.1% in Thailand, by 13.3% in Indonesia and again by 11.9% in India (Euromonitor). Investment in commercial infrastructures, essentially shopping centres, has grown on average by 28.5% p.a. since 2009 in China. However, the sector is driven by the growth of e-commerce. For China, this led to a 43% increase in sales in 2013 (EIU). The development of smartphones and the democratisation of the Internet in rural areas are catalysing the growth of the sector in emerging Asia. In India, 15% of the population has access to the Internet, against 7.5% in 2010 - effectively doubling the connected population. In the medium term, the main risk for the sector lies in the high level of household

debt in some of the region's countries (Korea, Malaysia, Thailand and Singapore in particular).

In this context of strong growth, the risk remains low in emerging Asia.

North America

The environment is hardening for the major retailers, despite the fall in unemployment in the United States (at 5.9% in September 2014) and sustained private consumption (+2.4% year on year in Q2 2014). Inequalities are growing and consumer habits are changing. The world's number one retailer and biggest employer in the United States, Walmart, has therefore lowered its sales growth forecast for 2014. The growth rate is expected to drop from 3-5% annually, to 2-3%. In response, the distribution giant will considerably increase its investment in e-commerce, which currently stands at \$1 billion, by 20% to 50%. However, with end-of-year sales representing between 20% and 25% of annual turnover for retailers, they are now multiplying promotions and the prospects are favourable. The fall in oil barrel prices (which has just reached its lowest point since June 2012 at \$80) is expected to boost the purchasing and travel power of households, which will be more inclined to increase their spending for the end-of-year festivities.

Our risk assessment is therefore still low.

5 TEXTILE-CLOTHING

Manufacturers in the sector are improving their margins thanks to the fall in the price of raw materials - particularly cotton, which is at its lowest since 2010 (at 62 cents a pound for delivery in December). This is explained by the abundant supply and the fall in Chinese demand. Emerging Asia remains a dynamic area, but the reduction of duty-free import quotas in China from 2015 is expected to drive up the cost of raw materials on this key market. As for the developed economies, the Europeans are again buying clothing, while in North America the growth of the sector is slowing and seems to be stabilising.

Western Europe

After two difficult years, 2014 has been a year of recovery. Over the first half of 2014, textile and clothing manufacturers posted a 4% increase in their activity compared with the same period in 2013 (Euratex). The big European economies are beginning to consume clothing again, with positive sales growth since the beginning of the year. As an illustration, the clothing giant H&M recorded growth of 16.5% in its turnover over the last nine months (December to August), against only 3.8% over the whole of 2013.

With the positive trend with respect to demand likely to be confirmed, our assessment of the risk remains medium.

Emerging Asia

Still supported by demand, the sector is showing strong growth as evidenced by the opening of 51 new sale points in China by the Swedish firm H&M (+25%). E-commerce is also supporting this growth: Inditex has just launched sales lines in South Korea and H&M in China.

More up-stream, the cotton market has been shaken in Asia by the announcement of the Chinese authorities that they are reducing the duty-free import quota for cotton. In effect, the world No 1 cotton importer wants manufacturers to turn to the major domestic suppliers. As these are of lower quality, foreign supplies have usually been preferred. China will therefore reduce the volume of duty-free cotton to the minimum threshold set by the WTO at 894,000 tonnes, against about 1,500,000 tonnes in 2014. Beyond this limit, imports will be taxed at 40%. Already, over the first nine months of the year, China has imported 38% less cotton than a year ago. In the other emerging Asian countries, Indian production is expected to reach record heights this year, supported by favourable weather conditions, enabling India to become the No 1 world producer ahead of China. Clothing production in Bangladesh, which has the lowest hourly labour cost in the region (\$.68 per month against \$.70 in Vietnam and \$.74 in Indonesia) remains very dynamic. Indian and Chinese investment in the region will continue to support the sector.

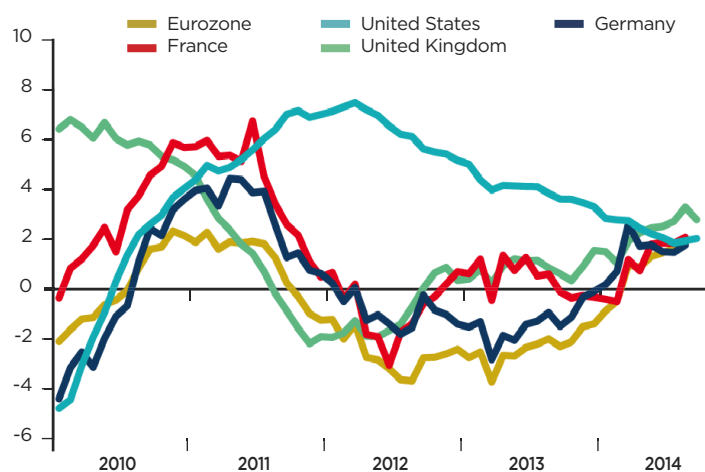
With strong demand and abundant cotton harvests, the sector remains robust. However the effects on local production costs due to the reduction in Chinese cotton imports still needs to be watched. Our risk assessment therefore remains medium.

North America

Cotton harvests for the 2014/1015 season will reach record volumes in the United States (the world's 3rd largest producer), with an expected volume growth of 3.8 million tonnes (ICAC). On the demand side, thanks to the healthy state of American employment, the sector has held up well compared to Europe. H&M has recorded a 22% rise in sales over the last ten months (December to August). Admittedly, the rate of growth is slowing but it is stabilising at around 2% in annual volume.

Our assessment of the risk remains medium.

Variations in clothing sales (% , volume, annual average)



Sources : Eurostat, U.S. Census Bureau

6 TRANSPORTATION

The sector's performance is closely linked to world growth and the dynamics of international trade. In 2014, world growth accelerated for the first time since 2010 and this trend should continue in 2015, even though the recovery is weaker than expected. It should coincide with stronger growth in world trade, forecast at 5% by Coface (against about 3% over the course of the last two years). In this context, passenger transport is showing strong performance even though the traditional European players are still facing difficulties⁽²⁾. The same goes for air freight, where Europe is also suffering from the effects of the Russian embargo on its trade. Finally, maritime

freight is growing in 2014, after a sluggish 2013. CMA CGM posted turnover growth of 3.2% over Q1 (-1.4% in 2013), while the Maersk group recorded growth of 1.6% over the same period (-4.3% in 2013).

Western Europe

Air passenger transport is very dynamic in the region. Over the first eight months of 2014, business grew by 6.1% (in RPK⁽³⁾, IATA). However, not all the airline companies are benefiting from this pick-up in demand. The low-cost carriers have grabbed the majority of the increase in demand.

(2) See Coface Panorama, "European airlines: forced to change", September 2014

(3) Revenue-Passenger-Kilometres, i.e. the revenue per kilometre travelled per passenger

Aircraft orders also show this dichotomy between the legacy and low-cost carriers. EasyJet has exercised options for 27 additional Airbus 320 planes and Ryanair has ordered 200 Boeing 737Max 200 aircraft. In contrast, Air Berlin has cancelled an order for 15 Boeing 787 and 18 Boeing 737 planes, in order to carry out a restructuring programme. In this strongly competitive context, the increase in airline tickets in Europe is continuing to slow, rising by an annual rate of only +0.6% in September 2014 (Eurostat).

The situation of the legacy airline companies needs particular attention. Our assessment of the risk remains medium.

Emerging Asia

The number of households with access to air travel is growing considerably and supporting the sector, which grew by 6.8% at the end of August (in RPK, IATA). Moreover, regional trade makes this region the most important in terms of air-freight, with a market share of 21.6% (IATA). Though the pace of GDP growth is stabilising, Asia will see the strongest growth in trade in 2014 (+5% in exports and +4% in imports according to the WTO). This will also support the growth of maritime freight.

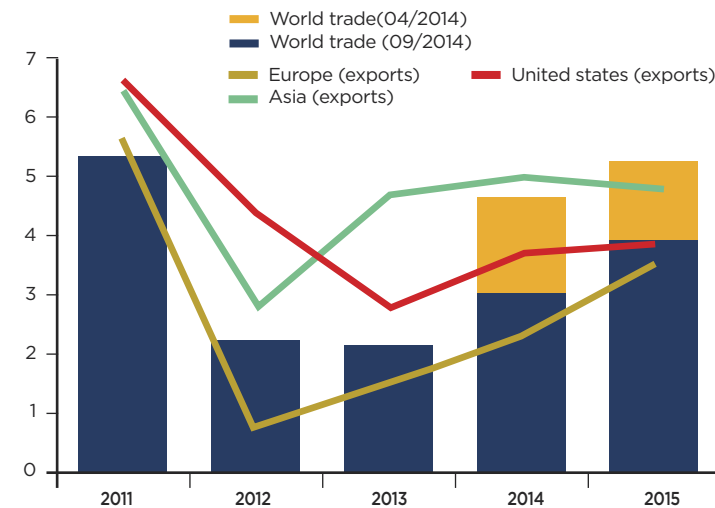
Our assessment of the risk remains medium.

North America

The air transport sector is benefiting from past restructuring. While the market is showing signs of maturity with growth of only 2.7% at the end of August (in RPK, IATA), the profitability of airlines remains above that observed in Europe. However, investments have been constrained by this restructuring. In the United States, the average age of aircraft fleets is 12.5 years - against 8.9 in Europe, 8.2 in Asia and 6.9 in the Middle East (IATA, 2013). In the long run, fleet renewals will hit airlines' margins. Meanwhile, the strength of growth in the United States will contribute to the resurgence of business class travel and freight transport.

Prospects remain favourable, thanks to the healthy state of American growth. As far as the air transport sector is concerned, carriers need to improve their financial health to demonstrate their ability to modernise their fleets. Our assessment of the risk therefore remains medium.

World trade and exports (% annual variation)



Source : WTO

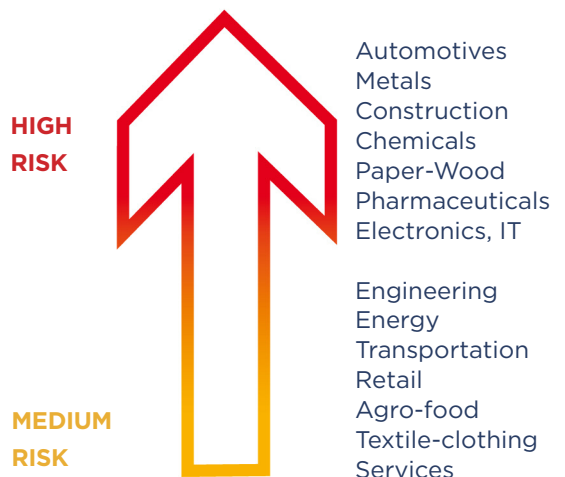
Sectorial risk assessment methodology

Coface's assessments are based on the financial data published by over 6,000 listed companies in three major geographic regions: Emerging Asia, North America and the European Union 15.

Our statistical credit risk indicator simultaneously summarises changes in four financial indicators: turnover, profitability, net indebtedness, and cash flow, completed by the claims recorded through our network.

Sectorial risk assessment

Hierarchy sectors in Western Europe



STUDY

EUROPEAN PHARMACEUTICAL COMPANIES: IS AUSTERITY FATAL?

BY OUR ECONOMISTS



Khalid AIT YAHIA
Economist

« Pharmaceutical companies are dealing with multiple challenges : constraint in health spending, competition from generic drugs, increasing State's regulation... »

The 2008-2009 crisis was felt by every sector of activity. It has durably affected the advanced economies, as shown by the exceptional slowness of the recovery. In our view, this is well illustrated by the pharmaceutical industry in Western Europe, as this industry was seriously undermined by the measures adopted by governments in difficulty to cut public spending. However, a revolution of a more qualitative nature impelled the players in this sector to change their strate-

gies, as well as their economic model, forcing them to reinvent themselves, to conquer new fields and new geographic areas. The sector has many strengths, which make us optimistic about the ability of pharmaceutical companies to seize these redeployment opportunities.

Is the sector capable of overcoming the new challenges facing it? Where are the sources of growth for the pharmaceutical companies in difficulty on their traditional markets?

To address the issues affecting the pharmaceutical world, we must first understand the factors influencing drug companies. We will do this by analysing the pressures exerted by the different crises they have faced since 2007. We will then highlight the new forces which are imposing a paradigm shift on companies, the new organisational models already implemented by these players and which offer new growth prospects in the short and medium term.

1

HAS THE PHARMACEUTICAL SECTOR SUFFERED FROM THE ECONOMIC CRISES?

Since the early 2000s and during the first round of the post-Lehman Brothers crisis, health spending on pharmaceuticals as a share of GDP increased. This expenditure rose from 7.3% of GDP in 2000, to 9.2% in 2009, according to the OECD. Nearly three quarters of the spending was, and continues to be, funded by governments - a situation which quickly became unsustainable in a context of persistently weakened growth. One of the peculiarities of the European health systems is that the public sector acts as paymaster for the services provided to the population, thereby giving it real power to control (or even fix) the price of medicines, as well as profit margins.

Confronted with the sovereign debt crisis, the pressure on governments to reduce their deficits increased dramatically. To maintain the supply of

care in the face of ever-increasing public demand, the public authorities put control measures in place ("ring-fencing"). We note, however, that the share of spending on medicines in total healthcare spending has been falling constantly for more than 10 years, down from 14.9% (in 2003) to 13.4% (in 2011).

A fact: lower spending on medicines since the crisis

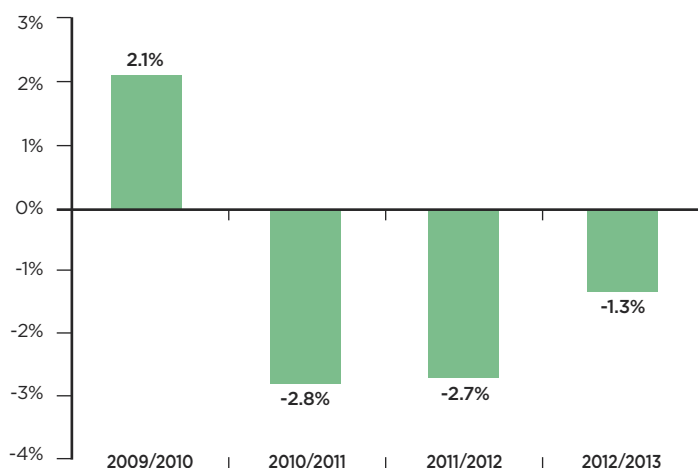
The pharmaceutical industry is regulated by public authorities because of the considerable health and social issues. Accordingly, the decisions taken by the authorities strongly influence the activities of pharmaceutical companies. Whether these decisions are marketing authorisations, or the determination of the amount of

reimbursement, dedicated public agencies exercise sovereign power over these aspects. The successive crises since 2007 have forced European governments to curb the rise in health spending.

Thus, as can be seen in Chart 1 below, sales of prescription medicines in the 5 major western European countries have been falling steadily since 2010.

Chart 1:

Change in prescription medicine sales by value in the European big 5 (France, Germany, United Kingdom, Italy and Spain)



Source : Evaluate Pharma

These negative changes are paradoxical in view of the underlying trends affecting western societies - and in particular those of Western Europe. Faced with an aging population with a high demand for healthcare (and affected by chronic illnesses that can prove disabling), healthcare spending would have been expected to increase sharply, or at least to grow positively in recent years. It is the speed with which the authorities have limited spending on medicines that has been surprising.

Several reasons can be suggested to explain this fall. We present those which seem to us to be the most convincing.

Falling prices and policies favouring generic medicines

Well before the development of the 2007 crisis, European countries tried to keep the growth of pharmaceutical spending under control. According to the OECD, spending on medicines at current prices grew by 30% between 2003 and 2007. Several measures have been introduced to curb this rise, depending on the nature of each country's health system.

One of the best-known measures was to demand a cut in the prices not only for medicines still protected by patents, but also for generic medicines (as in France, Spain and Portugal). According to Deloitte, these cuts may lead to a chain reaction in other countries, which set their prices in accordance with those of the reference countries.

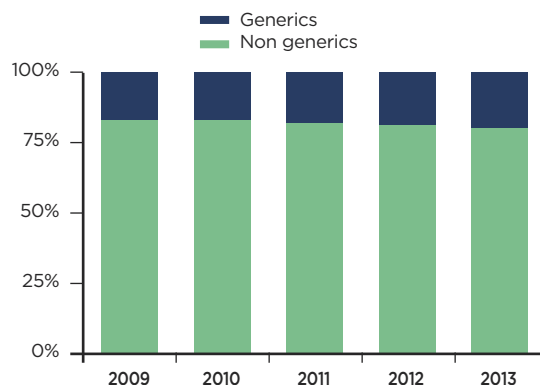
This is a "soft" measure, where rather than requiring pharmaceutical companies to lower their prices, governments argue that they do not want to pay more for products that costs less in neighbouring countries. Generally, the prices serving for comparison are those used by the British authorities, as they are considered among the cheapest in Europe. Thus countries such as France, Italy and Japan and Canada take the prices in the United Kingdom as a benchmark, thereby maximising the impact of the decisions taken in that country (which accounts for nearly a quarter of the world market for sales of pharmaceutical products).

Another common practice is to benefit from discounts on the part of the pharmaceutical companies, if the estimated budget for a drug is exceeded. Thus, if the total post-estimate cost exceeds the budget, the producer undertakes to pay all or part of the excess into the repayment system.

Finally, since well before the advent of the world crisis, most European countries have been trying to encourage the use of generics for medicines which have come into the public domain. Generic manufacturers obtain a permit to put their copy on the market several months before the patent for the original lapses and it really comes into the public domain. Doctors are rewarded for all prescriptions of generics, as are pharmacists who propose a generic substitute. In addition, the health insurance branch of the Social Security system in France gives higher refunds when the patient agrees to take a generic medicine. Chart 2 illustrates the increased use of generics to the detriment of protected medicines. Even though generics still only represent a quarter of the value of the drugs market, this share has been growing continuously for 5 years. Volume has increased more strongly and in 2013 the relationship was 46%-54% in favour of generics.

Chart 2:

Evolution in value of sales of generic drugs in Europe



Sources : IMS Health, MIDAS.

The crisis has therefore accelerated the reduction in health spending, in particular the amount devoted to medicines.

2 NEW SHOCKS TO ABSORB

Financial measures have been introduced, firstly to combat cost inflation resulting from medicine consumption, and secondly to curb the surge in consumption in the face of macro-economic shocks. In addition to the pressure due to the problems of public debt, problems specific to the sector are also affecting its situation.

The patent cliff

The patenting process for medicines works as follows. A pharmaceutical company, after having obtained a marketing authorisation from a Medicines Agency, has several years to recoup and profit from the sums it has invested in developing and marketing a new medicine. Several figures are circulating on the costs of a new molecule and on average this is currently nearly \$1.5 billion (against 1 billion at the beginning of the 2000s).

Given the colossal sums spent, a new medicine must be protected by a patent in order to guarantee the pharmaceutical company the right to benefit from the fruits of its research. In pharmaceutical jargon, a medicine that generates more than a \$1 billion a year is called a "blockbuster". The patent lasts for 20 years and therefore allows costs to be recovered, if marketing conditions do not harden in the meantime.

Pharmaceutical companies made great strides in terms of research during the 1980s. This period was followed by the marketing of medicines that have since become blockbusters. In the years since 2010, the pace of the loss of patents has accelerated, leading to a fall in revenues for these companies (Chart 3). Effectively, once a medicine loses its patent, it is quickly copied by a generic producer and the copy is authorised to enter the market before the target date for loss of the protection. The subsequent revenue decline is estimated to be between 75% and 90% of the previous year's sales - a decline which has accelerated since public authorities have been strongly encouraging the use of generic substitutes.

According to HIS, in Europe patents on Herceptin and Rituxan (Roche), Lantus (Sanofi), and Remicade (Merck & Co) will be expiring. This period will last until 2020, with a consequent loss in earnings between 2014 and 2016 estimated at over \$120 billion.

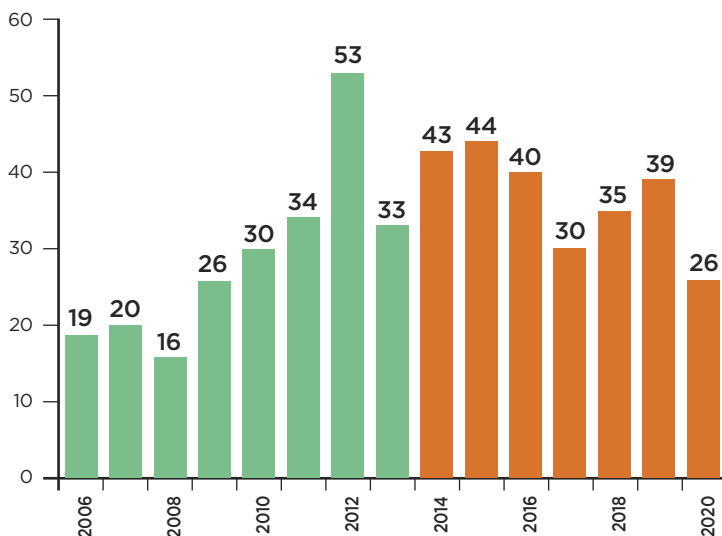
The value-based pricing

The regulated nature of the medication sector also affects the performance of the big European pharmaceutical companies. The influence of government agencies makes itself felt throughout all the key stages in the product's life. A medicine must obtain a marketing authorisation (from a medicines agency) before it can be made available in pharmacies). It must also be able to prove that it is not harmful to patients and that it has real therapeutic value. In our public healthcare systems, a paying agency takes responsibility for all or part of the price of the medicine, in order to guarantee indiscriminate universal access to health care. This paying body will decide to reimburse only after having carried out a rigorous cost-benefit analysis of the treatment. The pharmaceutical company must therefore prove that the new treatment brings value to the patient (Value Based Medicine, VBM) in terms of quality of life and/or additional length of life, relative to the cost (the price) borne by society.

This is particularly the case for treatments for complex, and hitherto difficult to treat, pathologies, leading to a loss of control by pharmaceutical companies over their treatments, in favour of governments and public paying agencies.

It is interesting to note that these practices are increasingly important in European countries - and especially in the United Kingdom and Germany. For example, in the United Kingdom, NICE (National Institute for Health and Care Excellence), which depends on the NHS, compares the results of clinical trials in order to determine the clinical effectiveness of a treatment. Thus the determined value is set against the cost (the price asked by the pharmaceutical company), giving NICE the responsibility of approving or rejecting the possibility of refunding. This body is regularly decried for its rejections concerning the refunding of anti-cancer treatments.

Chart 3:
Sales of medicines whose patents are expiring,
in billions of dollars



Source : Evaluate Pharma

Generally the pharmaceutical company agrees to reduce its price in order to get NICE to guarantee its agreement on repayments. It is, however, necessary to take two elements into account. Firstly, faced with the problems posed by public opinion regarding these rejections, the Cameron-Clegg government has created a fund of £200 million to fund anti-cancer treatments, which is supposed to last until 2016. Secondly, since January 2014, the British public authorities have gone even further in the implementation of VBM by paying only for treatments that bring a real therapeutic improvement (“break-through drugs”) over existing treatments, rather than treatments that bring only a marginal improvement. This is in order to get around the development of ‘me-too’ medicines, which largely duplicate the therapeutic action of those already on the market, without bringing real improvements. So, if a new medicine brings only an incremental and not decisive result, the outcome of the consultation to decide whether the NHS can pay for it will be negative. In other words, to be able to benefit from a positive response from NICE, the medicine needs to give patients additional years of life at a cost acceptable to society.

The other European country which is acting as a pioneer in terms of implementing VBM is Germany. At the end of 2010, the Act on the Modernisation of the Medicinal Products Market was passed, to limit the cost of pharmaceutical products. As a result of this Act, for every new molecule or new combination of existing molecules, a cost-benefit approach has to be conducted by an evaluation agency (IQWiG) in order to specify its value for the patient. As value is a difficult concept to measure, it is the clinical benefit that is assessed. So, if a molecule is analysed as better in terms of clinical benefits than a reference treatment, it will be refunded at a higher price. However, if there is no possible basis for comparison, the company must accept a lower, non-negotiable price, which can be awkward for treatments which bring a real improvement in therapeutic areas where rare illnesses predominate. Some pharmaceutical companies have refused to market their new medicines in Germany because of these rules, which they consider unfair and for which the decision-making process is thought to be too complex and unpredictable. Boehringer-Ingelheim and Eli Lilly have, therefore, decided not to launch their Trajenta (a type 2 diabetes medicine) in Germany. However, AstraZeneca has been able to benefit from a price negotiated for its Brilique anticoagulant, as, according to the German assessment agency (IQWiG), it offered a real therapeutic improvement when compared with Sanofi’s Plavix.

A European agency judged too slowly?

Since November 2005, all new medicines must be approved by the European Medicines Agency (EMA) in order to be able to access European markets. For this reason a pharmaceutical company that wants to market its medicine must prove its clinical effectiveness, as well as the absence of any danger for patients. This is shown using the data collected from various clinical trials. Generally, the same data is used when the case is submitted for approval in the United States and in Europe. However, despite the relative similarity of the cases presented, the FDA (Federal Drug Agency) and the EMA have different approval times.

According to a study by Ramshi Shah published in September 2013 in the British Journal of Clinical Pharmacology, the EMA took an average of 410 days to deliver its approval for a class of anti-cancer drugs, while the FDA(...) took only 205 days. The causes of this difference are attributable to “clock stops”, or the demands of the authorities for clarifications from the pharmaceutical companies. The other factor is linked to the length of the final approval process by the European Commission after the CHMP (the body of scientists which effectively gives its agreement within the EMA) has approved the active agent. This time lag has been estimated, for this class of anti-cancer medicine, as 90 days on average.

Other factors can come into play and explain these longer delays on the European side. These include the fact that the EMA is a collegiate body in which the authorities of each country must give their agreement, whereas the FDA is a single federal authority. In addition, since 2012, there has been a rapid submission procedure in the United States, called the “Breakthrough Therapy Submission”. This makes it possible to grant faster market access for life-threatening illnesses. A year after its introduction, 30 out of 80 applications have been granted. A somewhat similar initiative taken by the EMA was launched in a pilot form in March 2014.

« State backed agencies play an essential role throughout the stages of a product life »

3 WHY IS AUSTRITY NOT FATAL?

Pharmaceutical companies therefore face the dual challenges of cuts in health spending and growing government regulation of their industry. To meet these challenges, they have had to set out to conquer new markets and new therapeutic domains, both niche and more remunerative, even if the research there is more complex and therefore more costly. Nevertheless, European pharmaceutical companies benefit from a good base in the developing countries, which are genuine reservoirs of growth for these groups.

Roche and Novartis illustrate the importance of this redeployment towards more remunerative domains for pharmaceutical companies.

The emerging countries ("pharmerging" markets), drivers of growth?

As with the automobile sector, players in the pharmaceutical industry are turning towards the developing countries in order to achieve the growth

lacking in their own traditional markets. Because the main European pharmaceutical firms have a good base in the emerging countries, they can use this to counterbalance their ailing European markets. Thus, as one can see in Chart 4, the big pharmaceutical companies' shares in sales of pharmaceutical products range from 14% to 36%.

Graph 5 illustrates the sales growth rates of these groups in the emerging countries. Except in the case of GSK and Merck KGaA, the industry shows real dynamism.

Table 1 illustrates the fact that growth in spending on medicines in 2017 will come from the dynamism of some emerging countries, primarily China, India and Brazil.

Table 1
Annual growth rate forecasts for medicine sales in the "Pharmerging" countries and in developed countries.

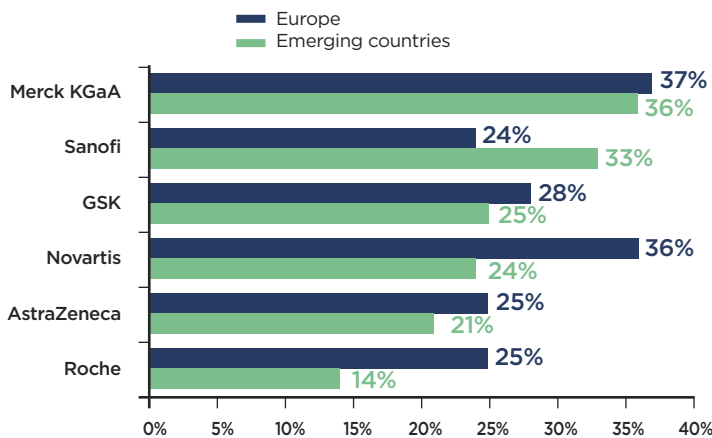
Developed markets	Pharmerging
Germany 1 - 4%	China 15 - 18%
France (-1) - 2%	Brazil 11 - 14%
Italy 0 - 3%	Russia 9 - 12%
Spain (-4) - (-1)%	India 11 - 14%
United Kingdom 1 - 4%	
Advanced 1 - 4%	Pharmerging 11 - 14%

Sources : IMS

Several factors may explain this dynamism.

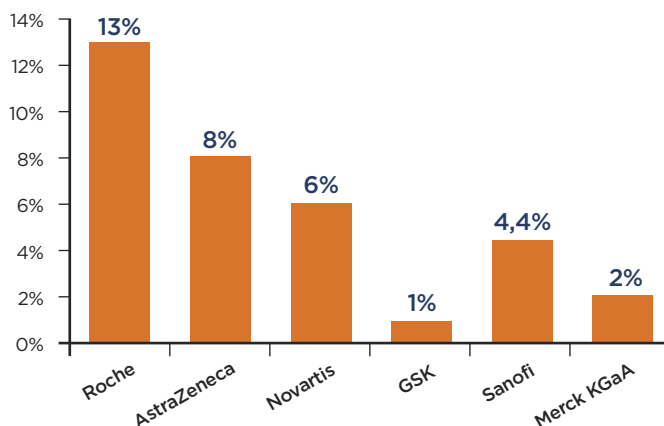
Firstly, the population of emerging countries is aging rapidly. Chart 6 page 14 below shows that the proportion of over 50 year-olds has been growing over the last 16 years. A few years ago, these countries were still known as having young populations. A demographic revolution is taking place. China, for example, because of its one child policy, is losing its demographic dividend and is seeing its proportion of over 50s reaching 28% of the total population. An aged population consumes more pharmaceutical products compared with younger age brackets. However, these seniors must be given access to healthcare. This funding gap due to aging and the prevalence of new illnesses is being tackled head-on by governments, in order to guarantee medical cover to older people, whether employed or not. Thus, in the early 2010s, China extended the public health insurance system to the elderly, after having previously favoured private cover in the 1980s. In 2003 Brazil passed an Older Persons Law, which aims to improve the quality of life of the oldest, with a health programme which facilitates access to care and particularly to pharmaceutical products in public health institutions.

Chart 4:
Major European groups' shares of sales in emerging countries and Europe in 2013.



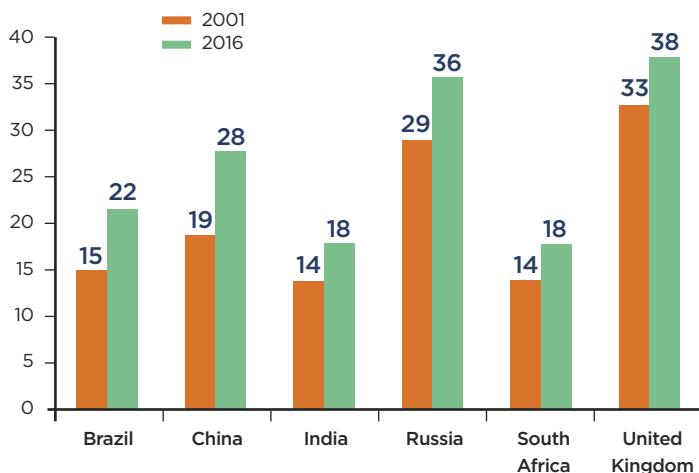
Source : The companies' published accounts

Chart 5:
Sales growth rates of the major European groups in emerging countries



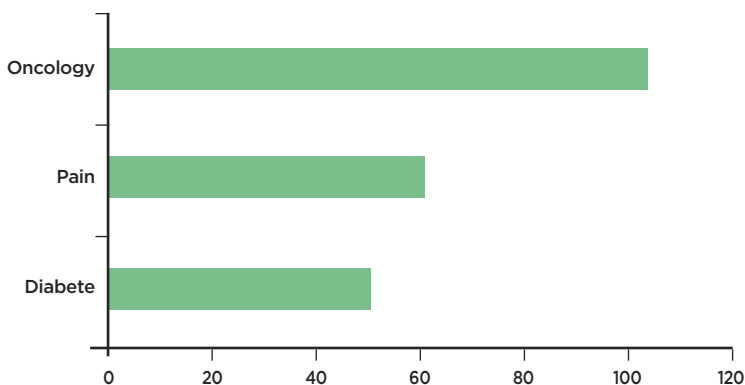
Source : Companies' published accounts

Chart 6:
Comparison of the proportion of over-50s in the population of some emerging countries



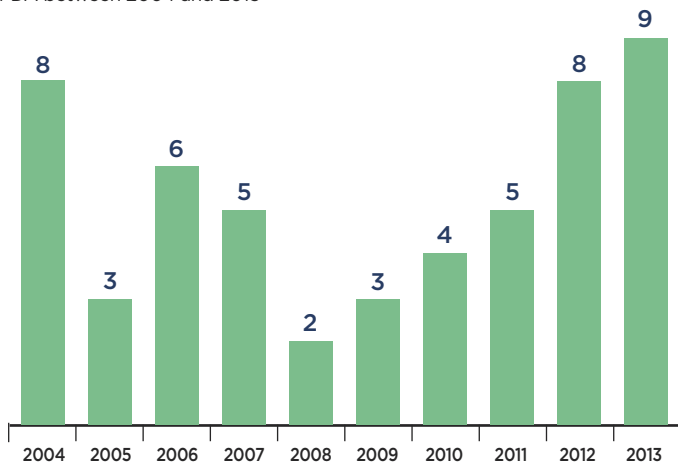
Source : EIU

Chart 7:
Sales in billions of US dollars, in 2017, for the three most important therapeutic areas



Source : IMS Health

Chart 8:
Number of medicines in the three most important therapeutic areas approved by the FDA between 2004 and 2013



Source : IMS Health

Another factor is the prevalence of new pathologies linked to life style. The economic development of the emerging countries tends to set them on the trajectories already followed by the developed countries. Thus, from a health perspective, the rapid development of illnesses linked to obesity is a characteristic shared by countries such as China, Mexico and Saudi Arabia - where cases of diabetes and cardio-vascular diseases are on the rise. These pathologies require high consumption of medicines. In fighting chronic illnesses, particularly cardiovascular diseases and diabetes, the three most prescribed medicines in the emerging countries are Plavix, Liptor and Lantus. According to the IMS, they total over \$1.6 billion in the emerging countries. Sales of medicines in emerging countries are expected to reach \$400 billion in 2017 (against about \$220 billion in 2012), and to represent nearly a quarter of world sales. Nevertheless, although the pharmerging countries seem to constitute an Eldorado for the world's pharmaceutical firms, they are closely following the changes currently occurring in Europe and, in particular, the cost control measures. The authorities are accordingly demanding price cuts and making the conditions of access more difficult. Nevertheless, the price cuts are offset by the effect of bigger volumes.

The therapeutic areas of the future

The loss of patents on flagship medicines, together with the competition from generics, has impelled the pharmaceutical firms to target more remunerative complex pathologies.

These pathologies belong to therapeutic areas which are currently reporting a sharp increase in sales. We have seen that lifestyle influences the illnesses developed in the course of a person's life. Cancer and its many forms are proving to be a value-generating field for pharmaceutical companies in the developed world. As we are living longer and our food is richer, cases of cancer are increasing. Oncology is becoming an important therapeutic area. These are two new sources of sales.

Chart 7 is revealing in this regard. In 2017 oncology will occupy by far the leading position in therapeutic areas in 2017. The pharmaceutical firms are rushing towards increasingly complex and costly treatments, in order to unlock their value. This enthusiasm translates into a significant increase in the number of molecules in the pipeline (in the clinical trials phase). This trend is illustrated in Chart 8 below.

Partnerships are becoming necessary

Our societies find it hard to accept the development of these illnesses and they therefore agree to great financial efforts to cure them. The public authorities are involved through various research trusts and funds, managed under the aegis of public medical research agencies. Moreover, and this is a point worth emphasising, the pharmaceutical firms are increasingly collaborating with public medical research bodies and university centres in order to target the causes of certain illnesses which are difficult to treat. Sanofi is collaborating with the *Massachusetts General Hospital*, one of Harvard University's hospitals, in fighting cancerous tumours, in particular those related to the blood. The same goes for AstraZeneca, which is collaborating with *Cambridge University's Medical Research Centre* in the United Kingdom, on the detection of genes causing illnesses.

This genetic detection is a way of getting the refunding bodies to accept expensive treatments because by accompanying the treatments with a companion test, the companies are trying to extract the maximum value from their products. In effect, this enables a population of patients to be targeted, thus reducing suffering for particular illnesses, and consequently relieving pressure on the budgets of the different health insurance organisations. An example is breast cancer, which can be more serious where the gene HER2 is present. Roche, through its subsidiary, Ventana, has developed a test which indicates the presence of the gene. Those patients who test positive are treated with Kadcyra and Perjeta (both produced by Roche).

4 CONCLUSION

The European pharmaceutical firms are still suffering from the repercussions of a period of austerity in their domestic markets leading to a slowdown, or even a halt, in the growth of public spending on pharmaceutical products. Competition from generics, particularly when a patent expires, has added to the difficulties of a sector in a delicate situation. The application of cost-benefit comparison procedures by the reimbursement agencies, seeking to assess the value of treatment for each patient, is a further obstacle which is difficult to overcome. Uncertainty over the level of reimbursement for a medicine has led to a redefinition of the sector's economy.

As a result, European pharmaceutical companies need to redeploy and find new sources of profit. For this they have a good base in the emerging countries, where sales growth offsets the difficulties encountered in Europe. Moreover, in order to maximise their chance of success when medicines are approved, they are collaborating with public or private research institutions so as to target the most promising therapies. The fight against the illnesses of the 21st century is contributing to the development of high value-added medicines, enabling pharmaceutical companies to limit the impacts of the fiscal austerity that seems to be becoming permanent in Europe.

RESERVATION

This document is a summary reflecting the opinions and views of participants as interpreted and noted by Coface on the date it was written and based on available information. It may be modified at any time. The information, analyses and opinions contained in the document have been compiled on the basis of our understanding and interpretation of the discussions. However Coface does not, under any circumstances, guarantee the accuracy, completeness or reality of the data contained in it. The information, analyses and opinions are provided for information purposes and are only a supplement to information the reader may find elsewhere. Coface has no results-based obligation, but an obligation of means and assumes no responsibility for any losses incurred by the reader arising from use of the information, analyses and opinions contained in the document. This document and the analyses and opinions expressed in it are the sole property of Coface. The reader is permitted to view or reproduce them for internal use only, subject to clearly stating Coface's name and not altering or modifying the data. Any use, extraction, reproduction for public or commercial use is prohibited without Coface's prior agreement. Please refer to the legal notice on Coface's site.

Photo : © nikesidoroff - Layout : Les éditions stratégiques

COFACE SA

1, place Costes et Bellonte
92270 Bois-Colombes
France
www.coface.com

