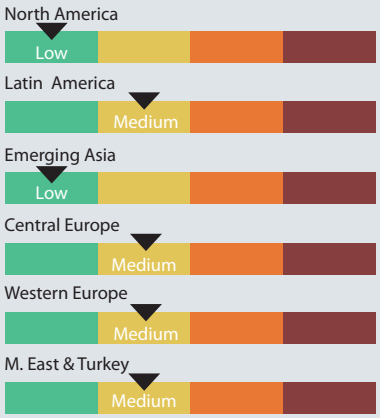
PHARMACEUTICALS

COFACE REGIONAL SECTOR RISK ASSESSMENT



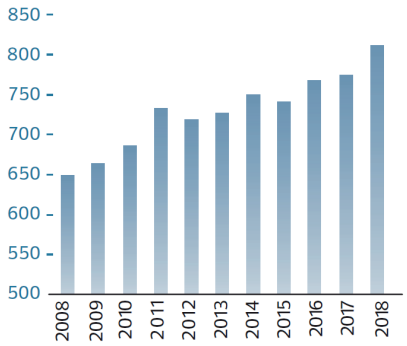
+ STRENGTHS

- Development of health insurance systems
- Robustness of US demand
- Demographic and lifestyle changes
- Pressure for access to innovation

- WEAKNESSES

- Quality problems with certain active ingredients in India and China
- Payers increasingly demanding in terms of costs and the real efficacy of new therapies

WORLD SALES OF DRUGS IN BILLIONS OF DOLLARS



Sources: IQVIA, formerly Quintiles IMS Health

RISK ASSESSMENT

Agencies in charge of health care provision (particularly the reimbursement of drug prices) face the approvals of high-cost treatments, while having to manage deficits arising from demographic changes.

In Western Europe (France, Italy, Spain, Germany and the UK) spending on prescription drugs is constantly growing. Accordingly, the deficits are increasing, e.g. those of the NHS in England and Wales. In France, the French health insurance deficit has narrowed slightly but nevertheless remains substantial (EUR 4.1 billion).

In the United States, drugs prices are on a regular upwards trajectory, in particular those linked with specialty medicines. Pharma groups saw their profits rise by 2.9% according to the Census Bureau. The authorities made numerous proposals to help curb this inflationary spiral ahead of the presidential election. The introduction of the Affordable Care Act (ACA, otherwise known as Obamacare) has led to increased healthcare spending, with the number of uninsured adults constantly falling since the enacting of this law.

The process of rebalancing the economy, now giving priority to domestic consumption, places an increased focus on meeting households' healthcare needs. The extension of the coverage for healthcare costs (although still partial) means the authorities need to keep a lid on costs, particularly those linked to drugs.

DEMAND

The cost of new therapies forces payers to keep a lid on spending. In 2018, the price control measures in force in Western Europe will still apply, despite growing demand linked to population ageing and lifestyle changes. For example in France, the measures taken to reduce spending (+2.3% for 2018) should continue to affect pharmaceutical companies, via price cuts, and favour the emphasis placed on the use of generics. The approval of expensive specialty drugs for smaller populations, mean regulators need to make difficult decisions on reimbursement levels and conditions (oncology, orphan diseases, etc.). For instance, in the United Kingdom, the nivolumab (opdivo) therapy developed by BMS Pharmaceuticals: the NICE (National Institute for Care Excellence) managed to get an undisclosed price reduction to allow this drug to be prescribed on the NHS through the Cancer Drug Fund (CDF).

In the US, sharp increases in insurance premiums for 2018 (expected to be between 16% and 18% depending on the plan) highlight the need to make drugs available at affordable prices. Indeed, after the numerous drugs related scandals that marked 2015 (e.g. Daraprim), the ramp-up of Obamacare, combined with the need to control healthcare spending (close to 17% of GDP, versus 9-11% in Western Europe), provides the background to the attempts aimed at regulating drug prices. According to the Milliman consulting firm, the average annual cost of healthcare spending for a US household was USD 26,944 dollars in 2017, up 4.32%. Our projection for 2018 is USD 28,020, an increase of 4%. Close to 42% of this amount is covered by the household, with only 58% by the "sponsor" (whether a private company, the federal state, or a local authority). The approval of a number of specialty drugs over many years has driven this cost up. Again according to Milliman, the cost of drugs in 2017 increased by 8%. Whilst this rise was slower than the preceding two years, it is still high and in particular the middle classes as the subsidies linked with the ACA are removed by President Trump.

In China, since the end of the first half of 2015, drug prices are no longer determined by public authorities, leaving it up to "market forces". Nevertheless, this opening masks a public determination (enshrined in law) to force the providers to offer reasonable prices, via negotiations with the regulators. However, it is worth pointing out that public insurance does not cover the most serious and costly illnesses.

SUPPLY

Research & Development spending is expected to pick up in 2018 (2,5%) according to Evaluate Pharma. Sales of drugs are expected to increase by 4.8% in 2018. This increase, which applies to all major world economies, will be a reflection of the expanding market in drugs treating orphan diseases.

In 2018, Coface estimates that spending on prescription drugs is set to grow by 4% for the top five EU countries (Germany, France, the UK, Italy and Spain), to reach almost 126 million EUR. This is explained by the increasing presence of specialty drugs (more than a third of total sales), even though payers are reluctant to pay the pharmaceutical companies' list prices.

In the US, the Federal Drug Agency (FDA, in charge of approving new drug registrations) is thought to have approved almost 35 new molecular entities (NME) at end-October 2017 compared with 20 in the preceding year. The majority of these entities belong to the fields of oncology and orphan diseases, not forgetting treatment of cardiovascular diseases. Coface estimates that sales of drugs, whether associated with these new entities or not, should rise by 6% compared with 2017. In addition, the launch in the market of biosimilars (the "generics" of biological drugs) should also help slow the increase in drugs expenditure. Finally, there is the uncertainty surrounding the future of Obamacare, which could impact on the growth in healthcare spending.

In relation to the size of its population, Chinese spending on drugs as measured by IMS Health, which produces many analyses relating to healthcare and drugs, stood at around USD 119 billion in 2016. Coface estimates that sales should grow by 4% in 2017 and 2018 to reach USD 128 billion. There are however two major risks to note: the lack of transparency during public tenders and measures to control health spending in China. The health authorities would in fact like to limit prices of imported drugs (which are generally the most innovative), especially in oncology. Although 96% of the population has public health insurance, this regime does fully cover the most expensive treatments. In addition, public authorities have heightened their vigilance concerning the practices of pharmaceuticals companies, especially foreign ones.