

June 2023



Our Trade Sector Experts



The Americas: Patrick Scardina, Atradius' Manager, Regional Underwriting in Irvine, California, USA

Patrick started his career as a Risk Services' intern for Atradius in Baltimore, Maryland, in 2008 before becoming Associate Underwriter, CTC Underwriter, and Sector Underwriter. In January 2014 he relocated to California to manage Atradius' West Coast Regional Underwriting. In April 2022, Patrick was promoted to Manager, Regional Underwriting and now looks after the Regional Underwriting Team across the United States. Pharmaceuticals is one of his areas of sector expertise, where he acts as a strategic thinker, priding himself on finding innovative solutions.



Asia Pacific: Judy Ji, Atradius Senior Underwriter in Shanghai, China

Judy has been working with Atradius for 15 years, following her time as an auditor with PwC. Her work has always been as a mainstream risk underwriter, with currently a special focus on pharmaceuticals and metals. In addition, she has also worked closely with the ICT, machines and food sectors in the past. Judy is based in Shanghai in China. One of her strengths is in identifying risks and completing robust financial analysis.



Europe: Rubén del Río Hernández, Team Leader Large Buyer Unit at Atradius CyC, Madrid, Spain

Rubén has worked with Atradius CyC since 2005 and is currently the Team Leader of Atradius' Large Buyer Unit, where he had previously worked as Senior Analyst. He is based in Madrid, Spain. The Large Buyer Unit team combines a range of expertise and includes Pharma, Chemistry, Oil & Gas, Plastic, Cosmetics, Textiles and Hospitality among areas of specialist knowledge. In addition to the expertise Rubén developed on these sectors, he is experienced in the assessment of liquidity and solvency of companies.

Contents

Pharmaceuticals performance: global and regional outlook	4
What is the financial strength of pharmaceuticals producers?	6
To what extent do government health policies and regulations impact the industry?	9
Do pharmaceuticals businesses have good access to external financing?	9
What impact will ageing populations have on healthcare systems?	10
Will reshoring secure domestic pharmaceuticals provision?	11
Does the next patent cliff pose a risk to the industry?	12
What opportunities do pharmaceuticals present to emerging markets?	12
What are the environmental issues facing the pharmaceuticals industry?	14
Pharmaceuticals Top three opportunities and challenges over the next five years	15

Pharmaceuticals shows signs of continued strength despite weaker global economy

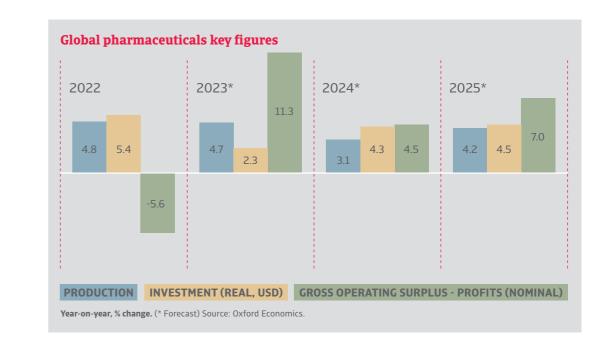
Outside of the spikes of the Covid years, the pharmaceuticals industry tends to follow a steadier path through economic ups and downs than other industries. However, now that vaccine demand is slowing, and the global economy is facing record levels of high inflation, what is the outlook for pharmaceuticals? We asked three of our dedicated Trade Sector Experts to share their knowledge and expertise on the key issues affecting the pharmaceuticals industry in their markets covering: the Americas, Asia Pacific and Europe.

What is the global outlook for the pharmaceutical industry?

Many areas of the pharmaceuticals industry experienced rapid growth during 2020 and 2021, largely thanks to the Covid-driven demand for vaccines and personal protective equipment. 2021 saw industry output growth of an astonishing 14%.

Although growth has now slowed significantly, this is not a case of boom then bust for the industry as we still expect global growth to remain above 3% over the next few years. Global high inflation is impacting consumer spending, however, and is likely to create the biggest dent areas such as personal hygiene and over the counter medicines.

The ending of China's zero-Covid policy at the beginning of 2023 has provided a boost for pharmaceuticals globally. The reopening of the Chinese economy is helping to reduce strains on global supply chains and, in particular, global access to the active pharmaceutical ingredients (APIs) produced in China.



Asia-Pacific drives growth momentum

Judy Ji is Atradius Senior Underwriter in Shanghai, China. Her work involves a strong view of Asia-Pacific and she is the Atradius pharmaceuticals expert for Asia. She noted: "The greatest rates of growth in the global pharmaceuticals industry will be seen in Asia-Pacific over the next few years." Pharmaceutical production and sales will grow by more than 5% year-on-year in 2023 and more than 6% in the years 2024 and 2025 respectively.

Much of this growth will be driven by increased demand in emerging economies, as healthcare systems improve and household incomes expand. Producers of generics and over the counter medicines will be the first to benefit, especially in China, India and Southeast Asia. In addition, Asia-Pacific's share of global pharma production will increase from 36% in 2022, to 42% in 2030. China's share of global production will grow from 25% in 2022, to 30% in 2030.



Asia-Pacific's share of global pharma production will increase to more than 40% in 2030.



Americas experiences modest growth in the coming two years

Patrick Scardina is Atradius Manager Regional Underwriting in Irvine, USA and has specialist insight into the pharmaceuticals industry in the Americas. He explained: "Pharmaceuticals growth in the Americas is forecasted to be in the low single digits in the coming two years. This follows the double-digit growth we saw in 2021 and early 2022 which was largely driven by Covid demand, namely vaccines, therapeutics, medicines, testing, and PPE. This segment is now declining in the double digits off the 2020 to early-2022 highs, while offset by strong performance of medicines geared towards fighting cancer, diabetes, and other life-threatening diseases."

He added: "The moderating sales growth expectations are likely to be a short-term dip. The long-term outlook is more positive, buoyed by ongoing demand driven by the ageing population and hopes for a combo Covid/seasonal flu vaccine, which has been delayed by the FDA until at least 2024."





Europe growth cools amid high energy prices

As the Team Leader Large Buyer Unit at Atradius CyC, Madrid, Spain Rubén del Río Hernández has a special insight into the pharmaceuticals industry in Europe. He said: "Although largely remaining on a solid footing, pharmaceuticals output growth in Europe is slowing amid high energy price headwinds. These are affecting the industry directly through the cost of fuel and indirectly through the increased cost of producing feedstocks and APIs." High levels of inflation across the region are also impacting high street spending and annual production growth is forecast to slow to about 4% in 2023 and 2% in 2024, after growing by 15% last year.

The long-term outlook for the sector in Europe is good. Pharmaceuticals firms will benefit from the region's ageing population and the resulting demand for pharmaceutical products to support both chronic illnesses and conditions associated with ageing. Strongest growth is likely to be seen in the major economies of the EU.

What is the financial strength of pharmaceuticals producers?

Asia-Pacific

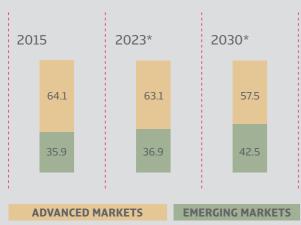
China's dominant position as the world's major drug production centre will help underpin the financial strength of pharmaceuticals industry in Asia-Pacific. In addition, most pharmaceuticals businesses in Japan and India have strong balance sheets and good access to bank financing. Ageing populations and expanding middle-classes in the region will support growth and the financial strength of pharma producers in the region.

Judy Ji noted: "In China, we expect the number of households with incomes over US\$35,000 to rise to 152 million in 2026, from an estimated 65 million in 2020. This will contribute to spending on high value-added pharmaceuticals. At the same time, the Chinese population is beginning to age, which will boost demand for pharmaceuticals related to chronic illnesses such as diabetes."

Emerging markets and ageing populations present greatest opportunities for growth

Improvements to healthcare systems in emerging markets present an increasing opportunity for growth. Although emerging markets will gain a rising share of global pharma output, this will not eclipse demand from advanced markets. Here ageing populations are driving growth, especially for chronic disease treatments and value-added speciality products.

Global pharma output: rising share of Emerging Markets



% of global production. (* Forecast). Source: Oxford Economics.

6

Some smaller pharma companies in Europe could face financing challenges due to high R&D investments needed.

Rubén del Río Hernández

Europe

Rubén del Río Hernández highlighted the different challenges facing different sizes of pharmaceuticals companies in Europe. He said: In Europe, large pharmaceuticals companies often have substantial financial resources due to their global operations, diversified product portfolios and extensive marketing networks. These companies invest significantly in R&D but also tend to have robust revenue streams from the sales of both patented drugs and generic versions."

He continued: "On the other hand, smaller pharmaceutical companies and specialist biotech firms may have more focused operations and smaller financial capacities. They often rely on venture capital funding or partnerships with larger companies to support their R&D efforts. These companies may be more susceptible to market volatility and may suffer from the consequences of higher financing costs."

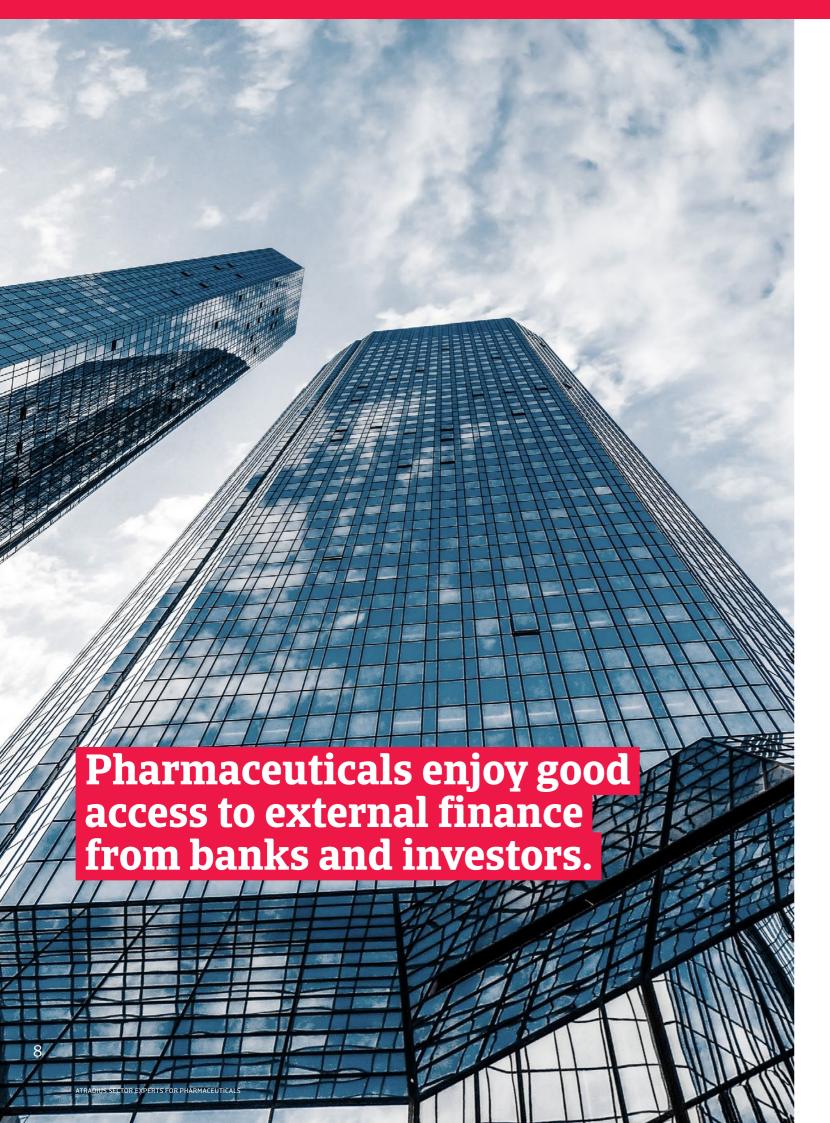
He concluded: "So, for the most part, the pharma financial indicators are strong but some medium and small companies could face financing challenges due to the high R&D investment required, the competition from companies based on India and China, and difficult access to financing at competitive interest rates."

Americas

The US pharmaceuticals sector is still susceptible to headwinds from inflationary pressures, as well labour shortages, product liability ligation and government pressures to reduce drug costs for consumers. However, despite this the sector is extremely resilient, with ongoing demand driven by an ageing population that will continue to fuel sector growth.

Patrick Scardina said: "Although pharma in the Americas tends to be dominated by a few players, the margins for branded pharmaceuticals are robust leading to strong cash flow, excellent credit profiles."





To what extent do government health policies and regulations impact the industry?

Government regulations and policies affect pharmaceuticals businesses throughout the world.

Americas

In the US the recently passed Inflation Reduction Act included a number of provisions that will change the pharmaceutical industry in both the short and long-term. These include a cap on monthly insulin costs for Medicare patients and the ability for the government to negotiate drug prices.

Looking the changes in the US, Patrick Scardina said: "These provisions will take some time to phase in and will not have a material impact on the creditworthiness of pharmaceutical drugs companies in light of their earnings power. However, the healthcare system, particularly hospitals and insurance companies with heavy government payers, may feel the pain on their already thin margins resulting from the intense pressures of labour inflation."

Asia-Pacific

Asia is also seeing changes to the regulatory landscape. With the Volume-based Procurement (VBP) policy and the National Reimbursement Drug List (NRDL), China has overhauled its health-care system. Global and domestic drug producers have to compete to sell their products in bulk to public hospitals. China has conducted seven rounds of centralized drug procurement since November 2018, the price decline has stabilized at around 50%.

In India, the government has announced a large incentive scheme to boost local API production and compete with China. Government healthcare policies in Japan are complex with a drug pricing system that is hard to predict (presenting a downside risk). Currently generics sales amount to 47% in volume terms, but the government aims to increase this share to 80%.

Europe

Most of the individual domestic markets in Europe are highly regulated and some feature constraints that can impact profits. For example, the businesses supplying France, Spain, Italy and the UK face pressure from health authorities to lower the prices of drugs and medicines. In Italy this includes a 3% margin cap for sales of prescription drugs.

Businesses in the UK additionally have to negotiate the additional red-tape presented post-Brexit. Border checks and regulatory burdens have raised costs and delayed delivery of goods. While some businesses have relocated to Europe, many are already multinationals with a presence in Europe. However, a significant level of unknowns still remain for the industry in the UK.

Looking at Europe more broadly Rubén del Río Hernández said: "There are some EU policies that may positively impact the sector's performance and growth in Europe in the coming years. For example, the EU Commission is proposing to revise the EU's pharmaceutical legislation, which includes the strategic importance of API production in Europe."

Do pharmaceuticals businesses have good access to external financing?

In general, the industry has robust equity, solvency and liquidity. Pharmaceutical producers and biotech businesses across the world largely enjoy good access to external financing from banks and investors, which helps to sustain high R&D expenditures.

Businesses in some markets are highly geared, but even these are able to generate healthy margins and attract investment. In China, for example, it's common to see companies with gearing around 100%. For some countries, such as India, both gearing and dependence on bank finance are low.

We also expect M&A activity to pick up during 2023 and 'normalise' to pre-pandemic levels. This will in part be driven by the fact that many pharmaceuticals companies appear to have financial strength or have ample liquidity sources in the financial markets.



66

10

In the US, growing pharma demand from Baby Boomers drive mid- and long-term growth.

Patrick Scardina

What impact will ageing populations have on healthcare systems?

In advanced economies and developed nations, people are living for longer, often with several chronic health conditions. While ageing populations inevitably place additional pressure on healthcare systems and government expenditure, they also present opportunities for the pharmaceuticals industry. This will mainly benefit producers of speciality products and medicines for chronic conditions, but also manufacturers of generic drugs. This is the case for the majority of Europe and North America, as well as Asia-Pacific, particularly Japan and China.

Will reshoring secure domestic pharmaceuticals provision?

Reshoring has been a hot topic in recent years. In 2020 President Trump signed an executive order designed to encourage the reshoring of pharmaceuticals manufacturing to the US. This is a position maintained by the Biden administration, driven in part by the desire for domestic drug security.

However, moving pharmaceuticals production is not simple. Regulatory clearance is required at every stage of the process, a time-consuming endeavour that could erode the earning potential of a drug that may already face deadlines in the form of patent end of life. In addition, producers in North America and Europe can struggle to compete with lower labour costs in Asia. Patrick Scardina acknowledged this and said: "The US only makes up an estimated 5% of global market share in APIs, as domestic facilities have struggled to compete against large-scale, low-cost factories overseas, predominantly in China and India. Concerns over intellectual property also favour retaining production in the US and Europe, rather than shifting the production of value-added pharmaceuticals to low-cost centres."



Rubén del Río Hernández agreed with this view and added the European perspective. He said: "The active pharmaceutical ingredient (API) manufacturing market has been dominated by India and China for several years. For this reason, the European Union (EU) is making efforts to reduce dependency on these countries and establish its own API manufacturing capabilities. These efforts will not only contribute to the economic growth of the European pharmaceutical industry but will also strengthen Europe's position as a global leader in healthcare innovation and production."

11

Does the next patent cliff pose a risk to the industry?

Several major drugs are approaching the end of their exclusivity rights over the next decade, including AbbVie's Humira, Johnson & Johnson's Stelara this year. While without question the ending of patent exclusivity will impact income generation and force the producer into competition on each drug, the vast majority will have been prepared with plans in place for some time. For some, ongoing R&D will see new patents take their place, for others marketing and sales strategies will promote competition. As Patrick Scardina noted: "In total, most branded drugs are set to lose exclusivity by the end of the decade, so near and long-term patent exclusivity losses will drive continued investment in R&D and M&A."

The ending of patent exclusivity is an area affecting pharmaceuticals businesses in the US and Europe. Although Japanese brand-name producers acknowledge the need for additional investment in the development of new medicines, this is not an area that impacts China in the same way.

What opportunities do pharmaceuticals present to emerging markets?

While ageing populations present a growth driver for developed markets, many emerging markets are also finding growth opportunities in low-cost manufacturing. In particular the pandemic spurred drug producers in India and China to substantially increase their R&D spending.

India is increasingly emerging as a major competitor to China for the production of Active Pharmaceutical Ingredients (APIs), supported in large part by government incentives. In fact India is becoming one of the leading suppliers of generic drugs to the US. A downside risk to this potential growth area is US regulation. Judy Ji explained: "Exports could be impacted by resumption of US Food and Drug Administration (USFDA) inspections of Indian production plants. Failures to meet required quality standards could lead to lower sales to the US, and could have a negative effect on margins."

Chinese authorities have also investigated a significant number of counterfeit and inferior drugs over recent years, resulting in fines for breaching regulations.



13

ATRADIUS SECTOR EXPERTS FOR PHARMACEUTICALS



What are the environmental issues facing the pharmaceuticals industry?

The increasing awareness of pharmaceutical residues in our drinking waters and subsequent consumer backlash are forcing pharmaceutical companies to reduce pollution of waterways. Patrick Scardina said: "Water samples from large US cities such as Dallas, Las Vegas and New York have revealed contamination at harmful levels of concentration. These pose a threat to the UN Sustainable Development Goal of providing clean drinking water and sanitation for all by 2030 and is an area the industry needs to address." Authorities in the US are releasing funds to help address this issue and lower the amount of contaminants that are found in drinking water.

Clean energy transition is also an area of growth for the pharmaceuticals industry. AbbVie has committed to sourcing 100% of their energy from renewable sources by 2035. Further industry players will also continue rolling-out additional ESG initiatives to improve their environmental impacts.

14

In China the "14th Five-Year Plan for the Development of the Pharma Industry" requires the sector to improve the efficiency of resources, build a green industrial system and promote the low-carbon and circular development of the entire industrial chain. Judy Ji said: "At present, many pharma companies are working hard to build green plants and develop advanced environmental protection technology."

Pharmaceuticals | Top three opportunities and challenges over the next five years

Top three opportunities for the Americas

- **1.** Generic growth as patents come due for a large percentage of branded drugs over the next decade.
- **2.** Drugs derived from living cells or proteins (Biologics) as the exclusivity period is 12 years, compared to 5 years as typically granted for small molecule pharmaceuticals.
- **3.** Growing demand from Baby Boomers as they are currently in the ages of 59-77 and will become more dependent on pharmaceuticals as they age.

Top three challenges for the Americas

- **1.** Government pressure to reduce prices, by way of the Inflation Reduction Act, insulin pricing caps and other similar measures.
- **2.** Political change in 2024 that could include the ratification of the proposed corporate tax rate to 32.2% and dilute corporate earnings. However, this could only happen if the Democrats would win the White House and majorities in Congress. In case of a victory by the Republicans, the IRA-related measures could be scrapped.
- **3.** Product liability risk that continues to arise in the normal course of business for manufacturers, distributors and retailers, such as the recent opioid settlements.

Top three opportunities for Europe

- Growth generation by advancements in new therapies and treatment technologies, such as with the new mRNA vaccines.
- **2.** Changes in the way clinical trials can be undertaken (including speedier and concurrent testing which was introduced as a result of COVID-19).
- **3.** Embracing AI and big data analytics into drug development, clinical trials and patient care.

Top three challenges for **Europe**

- **1.** Regulatory burdens and the threat of licence suspensions present a risk to domestic market players.
- **2.** Patent expiration in coming years will be an advantage for emerging market competitors.
- **3.** Shortages of medicines and the competition in the procurement of medicines between countries.

Top three opportunities for Asia-Pacific

- **1.** Strong demand driven by rising household income and growing middle class in emerging markets and ageing population in developed countries.
- **2.** Government initiatives to increase access to healthcare systems and reduce healthcare costs.
- 3. Digital technology improving efficiency and promoting industrial transformation, including AI research and development, intelligent manufacturing, hospital information, auxiliary diagnosis, telemedicine, smart warehousing, etc.

Top three challenges for <u>Asia-Pacific</u>

- **1.** Reform of drug pricing schemes could put pressure on markets in China and Japan.
- 2. Increased costs of raw materials, labour, energy, transport and R&D costs are a challenge for the region and add to the costs of innovation transformation in China and expiry of patents in Japan.
- **3.** Greater investment is needed to ensure quality inspections (both domestic in China and international such as US inspections of production plants in India).

15

ATRADIUS SECTOR EXPERTS FOR PHARMACEUTICALS





Atradius on social media youtube.com/user/atradiusgroup linkedin.com/company/atradius twitter.com/atradius

Copyright © Atradius N.V. 2023

Disclaimer: This publication is provided for information purposes only and is not intended as investment advice, legal advice or as a recommendation as to particular transactions, investments or strategies to any reader. Readers must make their own independent decisions, commercial or otherwise, regarding the information provided. While we have made every attempt to ensure that the information contained in this publication has been obtained from reliable sources, Atradius is not responsible for any errors or omissions, or for the results obtained from the use of this information. All information in this publication is provided as is, with no guarantee of completeness, accuracy, timeliness or of the results obtained from its use, and without warranty of any kind, express or implied. In no event will Atradius, its related partnerships or corporations, or the partners, agents or employees thereof, be liable to you or anyone else for any decision made or action taken in reliance on the information in this publication or for any loss of opportunity, loss of profit, loss of production, loss of business or indirect losses, special or similar damages of any kind, even if advised of the possibility of such losses or damages.

Atradius
David Ricardostraat 1 · 1066 JS Amsterdam
P.O. box 8982 · 1006 JD Amsterdam
The Netherlands
Phone: +31 (0)20 - 553 91 11

info@atradius.com www.atradius.com