"Italy is able to supply, with the help of other European manufacturers, about 90% of all European molecules, but this would require a massive simplification of national regulatory systems in target countries."

Paolo Russolo

PRESIDENT, ASCHIMFARMA – FEDERCHIMICA

ITALY (/COUNTRIES/ITALY) PHARMA & LIFE SCIENCES (/SECTORS/PHARMA-LIFE-SCIENCES)

May 28, 2021

Could you remind our audience of the main mandate of Aschimfarma?

As part of the Italian Federation of the Chemical Industry (Federchimica), Aschimfarma represents the manufacturers of APIs and intermediates for the pharmaceutical and biotechnology industries. The sector is made of about 72 companies with 109 production sites, and it accounts for a turnover of €4.3 billion – this is approximately 9% of the world's market. 11,900 people work in this sector. The API industry in Italy is very export-oriented, 90% of the total value being represented by export markets, of which 46% goes to Europe.

Italy's APIs industry is the largest in Europe. What are the industry's main strengths?

To start with, companies invest heavily in maximizing efficiencies and introducing new production techniques. The sector invests 3% of its turnover in applied research and 10% in plant optimization. Skills also represent an important competitive advantage: with labor costs exceeding the manufacturing average by 50%, the level of qualifications and professionalism is very high. Compared to other manufacturing industries, the number of R&D staff is twice as much in the pharma sector. Italy is recognized as a centre of excellence for research, technology and quality. Finally, our companies leverage on long-term relatonships of trust with customers from around the world.

How has the pandemic affected the API sector in Italy?

The chemical pharma sector grew in 2020, at a time when the chemicals and other industries suffered big declines. API production in fact grew at some sites driven by growing demand for drugs used in fighting the virus. The COVID-19 emergency highlighted the vulnerability of the European drug supply chain, which sources 74% of its starting materials and intermediates supplies for API production from Asia. This problem preceded the pandemic, and was accentuated by site accidents and factories' shutdowns in China and India in recent years. The pandemic further exacerbated the risks that the European health system is exposed to in a highly globalized and complex pharma supply chain. Whereas we can synthesize drugs in Europe, raw materials are no longer manufactured here.

How do you think Western pharma producers can mitigate raw materials dependency on Asia?

The need to have a robust and autonomous pharmaceutical supply chain is evident for all countries: China, the United States, India, Japan, and France have have already launched measures to make their supply chains more extensive and more sustainable. Europe's health autonomy will largely depend on its ability to maintain and develop its existing industrial base, as well as to invest in innovative and sustainable technologies. API producers are ready to accept this challenge, committing to work with the European Commission in order to create the best conditions to consolidate the pharmaceutical supply chain. Italy is able to supply, with the help of other European manufacturers, about 90% of all European molecules, but this would require a massive simplification of national regulatory systems in target countries. I am optimistic about the future of the Italian API sector and the medium-term forecast is positive.

What are the most significant trends and regulations shaping the industry?

There are various concrete initiatives at European and Italian level that go in the right direction. At the European level, the Pharmaceutical Strategy, communicated on 25 November 2020 and launched as "The EU Pharmaceutical Structured Dialogue" on 26 February 2021, is rolled out across 4 workstreams: definition of robust supply chain; causes and drivers of vulnerabilities and dependencies of supply chains; critical medical products; and innovation. Driving this strategy in Italy, the National Technology Cluster Life Sciences (ALISEI) is running a project for the "Reshoring of pharmaceuticals and active pharmaceutical ingredients in Italy." Some companies have already presented detailed development plans that are currently under examination by the Italian authorities.

How do you perceive the Italian regulatory framework for the API industry? How does it align to other international markets?

Currently, all drugs on the European market must comply with very stringent regulatory, quality and environmental standards and all the pharmaceutical companies are regularly monitored by European health and industrial agencies. For imported drugs, on the other hand, the quality guarantee is given by the audits of the importers and by the GMP certificates issued by the exporting countries. It is necessary that European agencies carry out the same GMP and environmental inspections outside of Europe, especially at API manufacturing sites. In order to simplify the regulatory system, we must accelerate the authorization processes for APIs and medicinal products. We also lobby for the global harmonization of the regulations across three dimensions: quality, safety and the environment.

What are Aschimfarma's priorities moving forward?

Our main agenda is to simplify and speed up the authorization process, identify the essential APIs that are at risk of running short, help secure better return on investment for the industry, and harmonize GMP and environmental inspections between European and non-European manufacturers.

(https://www.linkedin.com/shareArticle?mini=true&url=https://www.gbreports.com/interview/paolo-russolo_1&title=Paolo Russolo)

(/interview/salvatore-butti)

Salvatore Butti (/interview/salvatore-butti)

PRESIDENT, ASSOSALUTE - FEDERCHIMICA (/interview/salvatore-butti)

Assosalute represents non-prescription medical products in Italy and explains how easing regulations could be of huge benefit to Italians and the healthcare system.

ITALY (/COUNTRIES/ITALY) PHARMA & LIFE SCIENCES (/SECTORS/PHARMA-LIFE-SCIENCES)

(/interview/paul-carmel)

Paul Carmel (/interview/paul-carmel)

PRESIDENT & CEO, SIDEX (/interview/paul-carmel)

SIDEX explains how it provides financial stimulus to the exploration sector of the Québec mining industry.

MINING (/SECTORS/MINING) CANADA (/COUNTRIES/CANADA)

(/interview/dr-siva-samy)

Dr. Siva Samy (/interview/dr-siva-samy)

CEO & CHIEF PRODUCT STRATEGIST, VALGENESIS (/interview/dr-siva-samy)

ValGenesis explains how it streamlines the validation process to allow real-time access to validation documents and data enabling various stakeholders to achieve compliance efficiently.

UNITED STATES (/COUNTRIES/UNITED-STATES) PHARMA & LIFE SCIENCES (/SECTORS/PHARMA-LIFE-SCIENCES)

(/interview/michael-kauffman)

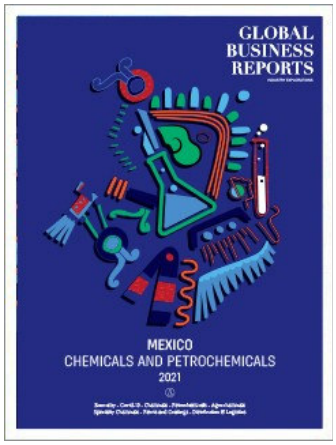
Michael Kauffman (/interview/michael-kauffman)

CEO, KARYOPHARM THERAPEUTICS (/interview/michael-kauffman)

GBR speaks to Karyopharm Therapeutics about the commercialization of XPOVIO.

UNITED STATES (/COUNTRIES/UNITED-STATES) PHARMA & LIFE SCIENCES (/SECTORS/PHARMA-LIFE-SCIENCES)

RECENTLY PUBLISHED



(/publication/mexico-chemicals-and-petrochemicals-2021)

Mexico Chemicals and Petrochemicals 2021 (/publication/mexico-chemicals-and-petrochemicals-2021)

MORE PREVIOUSLY PUBLISHED (/publications)

MACIG


(/interview/oscar-siviwe)

Oscar Siviwe (/interview/oscar-siviwe)

GENERAL MANAGER, TOP ENGINEERING SERVICES (/interview/oscar-siviwe)

Top Engineering Services offers local steel fabrication and engineering services for mines in DRC.

MINING (/SECTORS/MINING) DRC (/COUNTRIES/DRC) MACIG (/SECTORS/MINING?MACIG=1)

SUBSCRIBE TO OUR NEWSLETTER

(/subscription)

SUBSCRIBE TO OUR NEWSLETTER

- Get GBR content delivered to your inbox
- Receive industry based news
- Completely free, e-mail only

SUBSCRIBE NOW
(/subscription)

z