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Assobiotec's Leonardo Vingiani introduces the key trends shaping the Italian biotech ecosystem today, the steps that the country's government have taken to foster life sciences innovation, and the areas in which Italian biotechs truly excel globally.

How would you characterise the importance of the biotech industry within the Italian economy and what have been the most important trends of the past few years?

The Italian biotechnology ecosystem has continued its growth over the last five years supported by Assobiotec, a technological association that represents approximately 130 biotechnology companies and organizations across Italy. The association is divided between life sciences related to health, and bioeconomy, which is the agricultural and industrial use of biotechnology. While the growth of biotechnology in Italy began with the life sciences in the early 2000s, is only in the last ten years that the country has assisted to a significant growth of the sector.

Today, biotech companies from both life sciences and bioeconomy have the potential to affect 20 percent of the national GDP, creating the opportunity to innovate. Assobiotec's goal for Italy is to restart the growth of the economy to create more jobs and a better quality of life for its citizens.

The political goal of Italy today is to increase the level of innovation so that the entire Italian economy remains competitive. The importance of the biotechnology sector and its effect on a large portion of the national economy, greater than any single industry in the country, has the potential to regenerate the economic sector and further develop Italy scientifically.

What steps has the government taken to focus on building an innovation economy?

The biotechnology sector evaded the new legislation on tax credits for research. Moreover, new legislation was introduced for capital gains for investing in innovative start-ups and SMEs. Furthermore, the portion of the national budget dedicated to medicine for hospitals was increased, creating greater possibilities for innovation in the medical sector.

Additionally, a specific fund of one million euros has been created for general innovative medicines and innovative oncology medicines. There are also new investments into funds that invest in these ideas and stimulate the national venture capitalists to grow the financial market and create opportunities for innovative start-up companies. These new measures and funds are crucial for the growth of the biotechnology sector and of the Italian economy.

There are additional funds to stimulate new national venture capitals investments. This was needed due to the lack of venture capitalists at the national level with sufficient expertise to understand life science business plans. This lack of expertise created problems and made it challenging for promising Italian projects to find the resources to continue.

As a result of the distance from foreign investors in the US, international venture capital funds paired with local investors. Local investors are needed that specialize in life sciences and biotechnology and are now beginning to emerge. Finally, Assobiotec asked the government to create a new fund, a national passive investment fund, to match the private investment and strengthen the available capital and decrease the risk for private investors.

Is it difficult for Italian biotechs to attract and retain the talent profiles that they need?

Finding talent from abroad is not the issue. The main difficulty is creating suitable conditions to attract Italian talent working abroad back to the country. Currently, together with other stakeholders such as venture capitalists, we are working to create better framework conditions for top Italian biotech talent to return home.

What are the main infrastructure gaps in the Italian research environment today?

Italy is currently trying to solve the problem of technology transfer. Despite a lower investment in science than some other European countries, Italy and its researchers have created a good environment for science. However, the country needs to better focus on translating the knowledge and the quality of the knowledge into value for products and companies.

The new Italian government has created a new fund for technology transfer under the National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) and is also tasking the Human Tecnopole, an open research centre in Milan born out of the EXPO Milan 2015, with fostering collaboration and bringing added value to the scientific research ecosystem across

Italy and Europe.

In Italy, how big of a challenge is it for researchers to move between public and private sector jobs, as they frequently do in the US?

That is one part of the problem. Another aspect is the specific legislation in Italy that prohibits researchers from moving freely between university and industry. A cultural problem remains: research and business are considered separate. The truth is that they are linked and the movement between business and university needs to be opened to properly educate both sectors.

In which areas of the life sciences value chain does Italy have very well-developed expertise?

High-quality manufacturing remains a specialization for Italy and the country is the second biggest manufacturer in Europe. Italy is one of the global leaders in the world in the manufacturing of medicines although the crucial part of manufacturing is chemical products.

Assobiotech underlined this for the government and stated that if Italy wishes to remain relevant in manufacturing, industry and institution must work together to create conditions to attract more investment in the production of biotechnologies. If the country does not improve the production of biotechnology in the next decade, Italy risks to lose its leadership in the manufacturing space

Where do you feel that Italian biotechs and researchers should focus their energies moving forward?

Italy already has a good level of specialization in advanced therapy medicinal products (ATMPs). Furthermore, we have strong capabilities in producing medicines for rare disease. Because Italy only holds small and medium sized companies in the life sciences space, rare disease treatments for limited patient populations will be a key area of focus for the next decade.

Moreover, Italy is excellent in immunotherapy due to the number of clinical trials in this area conducted locally. Nevertheless, there is still room to grow and enrol even more patients in clinical trials because of the country's top-class healthcare infrastructure and expertise.

In my opinion, the two areas that Italy can grow the most are manufacturing and clinical trials due to the expertise available in the country and the space to create value. In regard, to research, this needs to be focused to niche areas over the next decade which could become a strength for the country.

Do you have a final message on behalf of Italian biotech?

The pandemic stressed the importance of life sciences. Following the first outbreak, vaccines and new therapeutics for the disease were discussed. This situation created a new environment in which spending on the life sciences was viewed as an investment rather than an expense.

This highlighted for the government the critical value of investing in the life science industry and its innovation. Collaboration is important in this regard to become a leader for the production and creation of knowledge that could be critical for health. This changed the attitude of society toward the

life science industry with the pandemic forcing us, unprepared, into a new type of collaboration.

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