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Life Sciences market

In the last decades the Italian pharmaceutical industry has undergone important changes. Phenomena such as competition from the emerging countries, the increasing cost of developing new drugs, the expiry of patents of the most widely used medicines, and the strong technological vocation of the sector have influenced and will continue to influence the domestic market.

To look at the future of the pharmaceutical industry, it is necessary to monitor also some significant demographic trends in progress, which represent important challenges for the sector and condition it globally. These trends include the increase in life expectancy, the reduction of child deaths, and the progressive aging of the population.

Looking at the numbers, we observe that life expectancy in OECD countries has grown by 5.5 years, from 75 years of life in 1990 to 80.5 years in 2015¹.

As for infant mortality, it is observed that while in 1900 more than 11 million children died before the age of 5, in 2016 the figure fell to 6 million; it is important to consider that about 60% of these deaths are caused by diseases that could be prevented with adequate vaccination coverage².

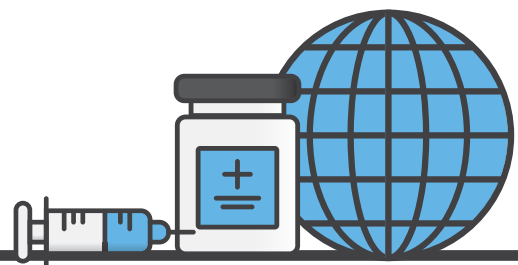
Finally, considering the progressive aging of the population, it is estimated that by 2020 the number of people aged over 65 will amount to about 604 million, or it will represent about 11% of the world population and 19.8% of the European population³.

A challenge for Italy, therefore, is to live up to a demographic panorama that already today raises big questions to the welfare systems of much of the Western world⁴.

Among the manufacturing activities, the pharmaceutical sector distinguishes itself by its technological relevance that characterizes the production processes: the manufacture of basic pharmaceutical products and pharmaceutical preparations relies, in fact, on the use of advanced and continuously updated technologies.

Because of its strategic importance, the pharmaceutical industry is a heritage that the country system must exploit at best, focusing on results to bring benefits both to patients and to the sustainability of the National Health System, and to the attractiveness of the country.

In order to support the growth of the Italian health system in terms of competitiveness and attractiveness, in the near future the challenge for our country will be to be focused on the high technological and scientific potential at its disposal, to create the favorable conditions for the development of innovation and the increase of investments in Italy in the coming years.



Domestic market

Pharmaceutical sector

The pharmaceutical industry remains a major development driver for the Italian economy. It represents, in fact, the leading market for growth rates. Over the years it has exceeded the average percentage of Italian manufacturing sectors and in 2016 it has increased its competitive advantage in relation to other productive sectors⁵.

The high level of competitiveness of pharmaceuticals compared to other industrial sectors is reflected in particular about the level of investments, the quality of human resources, and the international perspective. Considering the state of the Italian economy, still in the recovery phase, we understand how strategic it is for the country to invest in winning sectors with high potential such as pharmaceuticals to revive the growth of the entire country system.

The 2016 confirms Italy's position of excellence at European level: second only to Germany, Italy could further improve its positioning, if favorable conditions were created for further investments. The positive figure is influenced above all by the export activity, which reached 21 billion, equal to 71% of the total production⁶.

If we consider in detail the period from 2010 to 2016, we note that pharmaceutical exports have grown significantly more than the EU average (+ 52% compared to + 32%) and more than the export of all the Big Europeans⁷.

The Italian pharmaceutical industry consist of about 300 companies (including producers of raw materials and medicinal specialties). Taking into account turnover and parameters such as employment, investments, foreign sales, and taxes paid, the sector is composed of 40% of Italian-owned companies and 60% of foreign-owned companies.

On the employment side, the employment figure confirms the growth for the second consecutive year; it is also important to value the high quality of these human resources that allow to achieve high efficiency levels and represent an important factor of competitiveness and attraction for investments in the country. The high quality of the services requires pharmaceutical organizations to recruit talented figures, with skills in the digital and analytical field. One of our recent study in 2017, "Global Human Capital Trends", has identified some key drivers that will redefine the future of work, such as the cognitive technologies and the open talent economy. These two levers are leading many companies to reconsider their way of working, to design and organize their work, and to plan the future of the company itself⁸.

Biotechnology sector

The health biotechnology sector is one of the most research intensive sectors. It is currently experiencing a period of growth. This is a sector driven by biotechnological pharmaceutical innovation and it has led to the development of numerous therapies to tackle unmet clinical needs. In 2016, Italy shows a substantial stability in the total number of biotech companies: with a growth of 16 new operators, on the total of over 500 companies operating in the sector.

The Italian entrepreneurial fabric, linked to biotechnologies, is mostly made up of micro or small companies: about 3 out of 4 companies are small and more than half of these companies operate in the biotechnology market dedicated to human health (the so-called Red Biotech).

Looking at the territorial diffusion, over the 90% of the companies involved in biotechnology in Italy are located between

Lombardy, Lazio and Tuscany. Furthermore, with regard to total intra-muros R & D spending, there was a contraction relative to the last available year⁹.

Considering the Red Biotech area, Italy today shows off a recognized leadership position in the field of personalized therapy, advanced therapies, vaccines and orphan drugs for rare diseases. Given these positive elements, Italy's great opportunities to consolidate its leadership position in the sector could come from the creation of a system able to exploit even the smallest realities, which are the majority.

Doing so, Italy could be competitive on a global scale.

Generics and biosimilars

A high percentage of drugs with patent about to expire has influenced and will continue to influence the trend and demand for equivalent and biosimilar medicines. In 2017, 16 patents of drugs have expired, and this allows "generic" companies to produce equivalent medicines. To consider two medicinal products as equivalent, they must contain the same active ingredient with the same quantity and pharmaceutical form and they must guarantee the same efficacy and safety in use, even if specific therapeutic cycles are followed.

The future expiry of the patents for some active ingredients, therefore, will mean that a series of fairly high priced drugs will be joined by their "generic": an absolutely similar drug, with the same active ingredient, but produced by another pharmaceutical company, different from the one that patented it, at lower costs (and prices).

Medicines with expired patent account for over 90% of the packs reimbursed in Italy and 76% of the expenses charged to the National Health System. From 2011 to 2016, generics have increased their market share (from 14% to 21%), while the average value for packaging of expired patent drugs is lower than that of other European countries (-10%). On the sales side, the 2016 shows Italy as the first country in terms of value and quantity compared to the first 7 European markets and it represents 27% of sales of biosimilars. Our country is also first in terms of consumption per capita and of the consumption of the molecules for which biosimilar is available¹⁰.

Generics are growing in the market: according to Assogenerici's latest report on data from January to June 2017, the equivalent drugs represent 20% of the packaging market: there is an overall turnover of 1.54 billion, concentrated mainly in the class A drug market, for a total of 1.19 billion. The consumption is prevalent in the North: on the podium of the regions that consume more generic are the Autonomous Province of Trento, Lombardy, Emilia Romagna, Bolzano, Veneto, Friuli and Tuscany. At the opposite extreme we find Basilicata, Calabria, Campania and Sicily, where the generic is struggling to gain a foothold. Considering a high turnover of over one billion euros, with the reduction of prices it is estimated a saving of about 600 million euros. In some cases, the savings will be above all for patients (i.e. the Group C medicines, that are totally at the patient's expense); in other cases, however, the savings will be mainly for the national health system: drugs that have high costs and that

from 2018 they could be produced by other pharmaceutical companies. Combining traditional medicines with generic ones means for the National Health Service to have new resources available to invest in research and development or innovation.

Logistics sector

The introduction of the Bersani Law on liberalization (2006) has expanded the distribution of over-the-counter drugs, removing the exclusivity of selling to the public only to pharmacies and allowing parapharmacies and special spaces within the organized large-scale retail sale authorization. This is a sector in expansion: at the national level in the first 9 months of 2017 there were 571 new activations of parapharmacies throughout the national territory. The region with the highest number of openings of parapharmacies (physical or online) is Lombardy, with 71 activity codes reviewed. Then Sicily, with 62; third in Campania with 54, followed in turn by Lazio (51), Puglia (50) and Veneto (43). More than 8,700 codes have been filed for the opening and appear on the list made available online by the Ministry of Health.

The expansion of the distribution of medicines without a prescription has the objective of guaranteeing patients an easy and prompt availability, a correct and better preservation of what is on the market and the availability of on-site managers with specific professional requirements.

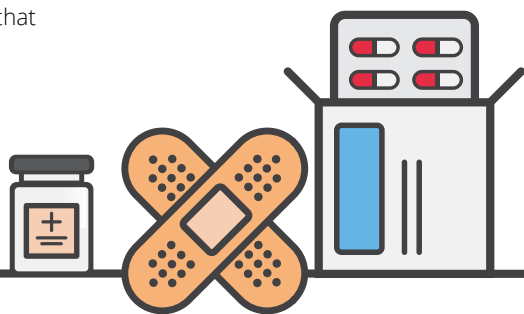
Medical device sector (medical technology)

According to Deloitte's forecast, Medtech sales will grow by 5.1% globally, from \$ 369 billion in 2015 to \$ 529.9 billion in 2022¹¹.

There are over 4 thousand companies operating in that sector in Italy: this market counts about 76,000 employees, 7.3% of which is employed in research and innovation, where companies invest about 1.1 billion euros, equal to 7% of the turnover. This figure, added to the export growth compared to 2015, makes Italy to the top positions among the 'patenting' countries on a global level.

The number of start-ups active in the sector are about 350, 44% of which are born as a spin-off of public research and operates in the most diverse sectors: advanced diagnostics (35%), oncology (10%), cardiovascular (8%), nutraceutical (8%), degenerative medicine (7%).

In Italy, the medical device industry is worth around € 7 billion towards the National Health System and € 4 billion towards the private sector: the domestic market in 2016 however showed a slight decrease (-1.6%), despite an increase of 10.3% in the three-year period 2013-2016¹².



Investments in research/innovation & costs control

The global growth of the Research pipeline shows that pharmaceutical innovation is experiencing a particularly flourishing phase, with more than 14,000 products under development, of which about half are in clinical phase. The 40% of the pipeline is represented by personalized medicine and biotech drugs. In this context, Italy is at the top of the world for the quality of scientific publications in medicine, pharmacology, drug discovery, oncology, cardiology and neurology.

According to some Deloitte's predictions, in 2022 the global pharmaceutical industry will use a lean operating model to generate research and development funding and provide more affordable medical innovations. The industrialization which involve the pharma sector has led to predictable increases in productivity in all its functions and geographical areas. Companies have gone through 3 evolutionary phases - first coding and standardizing processes, then automating them and now implementing Artificial Intelligence and machine learning to further increase the pace and productivity.

The traditional focus of "industrialising" finance and operations has been extended to a transformation focused on improving productivity across compliance, commercial development and discovery. This change of pace has improved compliance and has given greater predictability of core processes. Companies with the best track records in industrialization are driving

industry consolidation, leading to a 30% reduction in development cycle time and 40% improvement in productivity. Italy accounts for 7% of total global R & D investments: with 1.5 billion invested globally in 2016, the pharmaceutical industry is now the third largest manufacturing industry, first for both the share of innovative companies and for the ratio between expenses for innovation and employees¹³.

In 2016, the companies in Italy have invested 1.5 billion in research and 1.2 billion euros in high added value production plants: this is a figure higher by 3% compared to the previous year and grew by 20 percentage points in three years. Another significant figure of the positive effect of investments in the sector it is the growth of the average value of the exported products: an indicator that underlines the qualitative growth in terms of the medicines made in Italy¹⁴.

ROI on R&D investments

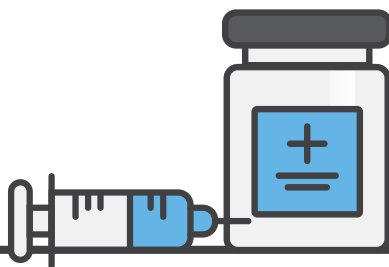
A specific Deloitte annual report "Measuring the return from pharmaceutical innovation 2017" provides estimates of the return on investment of 12 leading companies listed on the stock exchange, operating in the biomedical and pharmaceutical sectors. It analyses what companies could expect to obtain from current research projects, which are undergoing clinical development III. The analysis shows that while on the one hand the sector continues to innovate and provide new therapies / products, on the other hand the expected average returns relative to the

sample of companies explored continue to decline, with yields in 2017 reaching only 3.2% - a decrease of 0.5 % compared to 2016 and a drop of 6.9 percentage points compared to 2010. This corresponds to an average drop of almost one percentage point per year.

This average decrease is mainly attributable to the reduction of the products authorized for sale compared to the past, with an incidence of costs deriving from abandoned products therefore higher. In fact, 159 products are authorized in the reference period (1 May 2016 - 30 April 2017) against 182 of the corresponding period of the previous year: this is a decrease of 16% compared to 2016 and 17% compared to the average of the previous seven years.

This phenomenon could be interpreted in two ways: a positive one, according to which greater attention is paid to the introduction on the market of differentiating products, which entails a reduction of authorized products, and also an increase in costs deriving from the abandonment of projects that are not sufficiently performing; a negative one, which would show the difficulty of the sector in discovering and developing new products.

Despite the average cost to develop a product continues to rise to an average value of \$ 1,992 million, 2017 records the first sales increase per molecule / product since 2014, quantified at \$ 465 million, with an increase of \$ 71 million from 2016.



The data therefore show a significant greater effectiveness both in the development of truly innovative products and in the implementation of commercial policies.

Companies are increasingly focusing on niches of diseases and therapeutic areas that, therefore, allow them to achieve higher unit sales, but with a reduction of the number of produced drugs.

The sample of companies investigated does not show significant differences between very large companies, while the return on investment in the smaller company remains significantly higher, perhaps because they are more concentrated on a lower and selective number of “molecules / products”, which reduces the cost of so-called “failure”, i.e. projects that do not lead to the creation of a salable product.

Facing this decline in yields, companies are reacting by adopting both approaches aimed at positively influencing the commercial success of their businesses, which are aimed at containing costs, but above all they are evaluating the use of emerging technologies that have a huge potential for optimizing the value chain. The adoption of new technologies, such as artificial intelligence or robotic and cognitive automation (RCA), translates into a leaner operating model that can reduce research and development costs. In particular, innovative technologies can increase the productivity and efficiency with which drugs are discovered, developed and brought to patients. Companies are just starting to experiment with these technologies, forming innovation teams and funding tests.

The biomedical and pharmaceutical industry continues to face an incredibly challenging research and development environment and still needs to improve in terms of added value deriving from the investments made. However, for the first time there is a trend reversal represented by the increase in sales by product, partly due to the improvement of the efficiency of some R & D processes and partly from the introduction of more effective products, that they better meet the needs of the market.

The use of innovative technologies is only at the beginning and there are operational, cultural, regulatory and data accessibility / interoperability challenges in the process of scalar growth of their adoption. There is no doubt that investing in emerging technologies will have a positive impact both on the rise of cares and on cost efficiency.

Public costs control

Global pharmaceutical spending is expected to grow 5% annually in the period 2017-2021, growing more than twice the average of 2.2% for the period 2011-2016¹⁵.

Italy is the country with the lowest pharmaceutical spending among all the major European countries, despite a larger share of the elderly population; the price level of medicines is also lower than in other countries.

As shown by the main international indicators, the performance of our NHS ranks among the first in Europe and in the world, both in terms of quality of services and access to care. Improving the general level of health conditions is an important result in meeting health needs and containing social spending.

Considering the period January-June 2017, the net agreed pharmaceutical spending charged to the NHS increased, in comparison to the previous year (+ 0.8%). Consumption, expressed in number of recipes (just under 300 million recipes), shows a decrease of 0.5% compared to 2016, while the incidence of the ticket decreases by 1% (-6 million euros).

In 2016, public and private spending on medicines sold in pharmacies (including large scale retail trade and non-prescription drug parapharmacies) was € 17.5 billion, down 1.3% compared to 2015; while the public and private spending per-capita on medicines distributed in pharmacies in Italy was 289 euros in 2016, much lower than the average of the other Big EU (410 euros)¹⁶.

Total health expenditure grew by 1.0%, following the increase in both private (+ 0.3%) and public (+ 1.2%) spending.

Finally, compared to GDP, pharmaceutical spending in Italy is lower than the average of the Big Europeans (1% compared to 1.2%). Total public and private health expenditure in Italy is worth 9% of GDP, compared to 10% of the European average.

In order to maintain high quality standards, it is essential to consider the sustainability of the costs of the public health system through constant monitoring of costs and the quality of the services provided by the NHS throughout the national territory.



Italian excellence

International benchmarking

Looking at the historical price series of medicines, from 2001 to 2016, there is a general decline in all European countries, although faster in Italy. In fact, 2016 consolidates a downward trend in drug prices, which fell by a total of 32%, against an increase in inflation of 29%.

On the other hand, the decline (47%) of reimbursable medicines increased, due to the patent expiration dates and the cutting measures that took place over the years¹⁷.

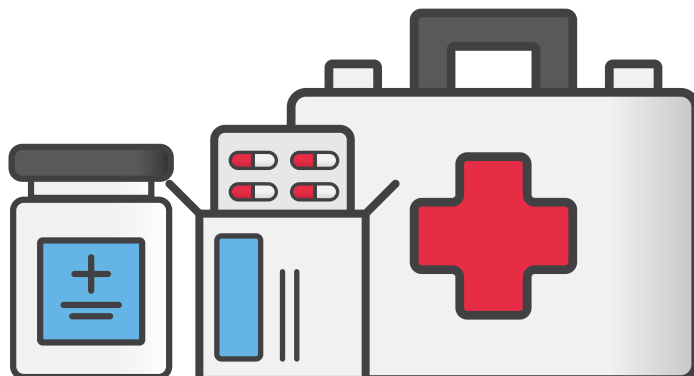
The trend in revenues is constant, where Italian companies record a very low average value that corresponds to almost half the EU average.

With regard to investments in the country, Italy is in first place in Europe as a destination country for investments of the most important multinational companies, in particular for American and German companies; while for British companies, Italy is considered as a global hub for vaccine production.

The technological innovation, the high quality of research and the creation of strategic partnerships lead to create new processes/products as well as new ways of operating that are recognized as the true excellence for our country.

All the extraordinary goals achieved by Italian researchers and local companies are the result of collaboration between individuals, the ability to be part of a network and the integration of skills between public and private staff. These elements can also trigger a real virtuous circle, able to develop skills and attract new and profitable investments.

In the coming years, drug companies in Italy will have to face the challenge of digital innovation, both in production and in research. In fact, the companies are moving towards intelligent robotics, and are investing in software to manage integrated orders, warehouse and production, but also they are focusing on the so-called technologies of additive manufacturing (i.e. 3D printing). Italy seems to have a solid foundation to become a hub of pharmaceutical innovation at all levels, so as to allow both the development of innovative therapies and a greater availability of resources, also for the NHS. However, it is necessary to overcome the difficulties related to bureaucratic constraints which limit access to innovative products, compared to the main EU countries.



A new approach to regulation

The contemporary digital society, with the important amount of information available, puts in place the issue related to data security, especially for companies operating in the health and pharmaceutical sectors. In fact, as shown in the 2017 Clusit Report, at international level the healthcare sector suffered the greatest increase in cyber-attacks in 2016 compared to 2015 (+ 102%). On the issue of data processing and protection, a new regulation at European level has been introduced on 24 May 2016, which will become directly applicable from 25 May 2018): the GDPR (General Data Protection Regulation). It is a real opportunity to improve the quality and safety of ICT services in health care, to protect both citizens who use social and health services, and professionals who provide them.

With the introduction of GDPR, therefore, a regulatory framework is established focusing on the duties and the responsibility of the Data Controller, which undertakes to respect the principles contained in it and to adopt the necessary tools, starting from a careful assessment of risks and impacts.

This framework implies two principles: the Privacy by design which concerns the need to design the Security and Privacy measures already in the design phase of the information systems and the Privacy by default, such as the ability to design the Security and Privacy measures by default, as a prerequisite for the normal operation of company information systems.

This implies for companies an adjustment both in the governance model, bearing in mind that the concept of an absolute security does not exist, and in adopting a different approach regarding their strategies and the go-to-market tactics. Furthermore, such legislation requires notification of the data breach, or notification, in case of violation of personal data.

At the organizational level, a new figure of the Data Protection Officer (RPD) has been introduced, who must have specific knowledge of the legislation (on privacy and security) and the practice of data protection. Another important implication for pharmaceutical companies is the creation (or use, if existing) of a document management system for all the reports produced on the protection of data for the purpose of exhibiting to third parties, aimed at demonstrating the activities in an objective and transparent manner implemented in compliance with the GDPR.

Most of the life sciences companies are trying to keep up with the changing regulatory landscape by implementing specific risk management and compliance initiatives, being aware that the legislator's actions will be a significant and ongoing challenge.

However, many of the actions which companies take to achieve compliance are useful not only at regulatory level, but also from a business point of view. The challenge for senior management will be to support the strategy and infrastructure flexibility in accordance with regulatory developments.

The drug companies therefore need to move forward, taking three key points into consideration:

- Regulatory strategy
- Business strategy
- Building infrastructure for governance, regulatory reporting, and risk management that scales and is flexible¹⁸.

All these planned interventions in the field of digital innovation, security and privacy are not "limitations" for companies, but can represent a real corporate flywheel, which has a global impact on companies, at a cultural, organizational, technological as well as economic level.

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