LIFE SCIENCE

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ITA
ITALIAN TRADE AGENCY

FOREWORD ON METHODOLOGY

The data contained in and employed for the present report was collected by Cerved Group through the exclusive processing of information from both public and private sources. The term 'public sources' is intended here as those available to the public, from institutions including but not limited to the OECD, the Italian National Statistics Institute (Istat), Assolombarda (Lombardy business industry association), ALISEI (the Advanced Life Science in Italy Technological Cluster), Federchimica-Assobiotech (the Italian chemical and biotech industry association), Confindustria Dispositivi Medici (Italy's medical devices industry association), Farmindustria (the Italian pharmaceutical industry association), Eurostat and the European Patent Office. The term 'private sources' is intended here as Cerved Group's proprietary databases on the major companies that operate in the life science industry.

The data collected has then been aggregated to build a complete picture of the life science sector, and broken down to distinguish between three main sub-sectors: pharmaceuticals, biotechnology and medical devices.

The companies that operate in the medical devices and biotechnology sub-sectors are registered under many different economic activity (ATECO) categories as their activities span many different sectors. For the pharmaceutical sub-sector, by contrast, the related companies are registered under following ATECO category:

- 21: MANUFACTURE OF BASIC AND FORMULATED PHARMACEUTICAL PRODUCTS, including:
  - ◊ 21.1: MANUFACTURE OF BASIC PHARMACEUTICAL PRODUCTS;
  - ◊ 21.2: MANUFACTURE OF MEDICINES AND FORMULATED PHARMACEUTICAL PRODUCTS.

All tables and graphs have been prepared by Cerved Group based on proprietary data and/or data from the public sources listed above.

LIFE SCIENCE AT A GLANCE

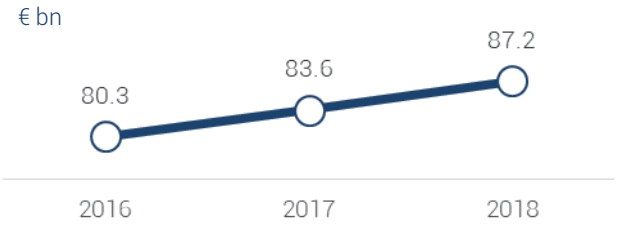
FOR BOTH THE ECONOMY AND INNOVATION, LIFE SCIENCE IS A STRATEGIC SECTOR BOTH NATIONALLY AND GLOBALLY.

IT IS THE 1 HIGH-TECH SECTOR FOR VENTURE CAPITAL AND PRIVATE EQUITY INVESTMENTS IN ITALY (€892 MILLION INVESTED IN 2018).

90% OF EMPLOYEES HAVE ADVANCED PROFESSIONAL QUALIFICATIONS.

4,949	155,850
COMPANIES	EMPLOYEES

LIFE SCIENCE: AGGREGATE REVENUE IN ITALY, 2016-2018



KEY REGIONAL CLUSTERS [a]

a) According to business industry association Assolombarda

LIFE SCIENCE AT A GLANCE

LIFE SCIENCE: REVENUE BREAKDOWN BY SEGMENT, 2018

2018; 100% = 87.2 Mld. €

PHARMA	291 COMPANIES	66,500 EMPLOYEES
MED DEVICES	3,957 COMPANIES	76,400 EMPLOYEES
BIOTECH	701 COMPANIES	12,950 EMPLOYEES

ITALY HAS 496 INNOVATIVE START-UPS AND SMES IN THE LIFE SCIENCE SECTOR[(a)]

FDI STOCKS AMOUNTED TO €6.914 BILLION IN 2018

IN 2018, R&D INVESTIMENTS REACHED €2.26 BILLION IN BIOTECH AND €1.65 BILLION IN PHARMACEUTICALS

R&D IN THE MEDICAL DEVICES SEGMENT WAS €2.20 BILLION[(b)]

a) Source: Chamber of Commerce. Businesses registered under Ateco categories 21.1; 26.6; 26.60.02; 26.60.09; 32.50.1; 32.50.2; 32.50.3; 32.50.4; 72.11

b) 2017 data (most recent year available)

HIGHLIGHTS

In Italy, the broad **life science** sector (including pharmaceuticals, biotechnology, medical devices, ICT solutions for healthcare and all corresponding service sectors) is, from an economic and technological point of view, one of the most **strategic and attractive** sectors, both in Italy and globally. Revenue, R&D investments and employment are all on the rise. In 2018, total **revenue** in the life science industry excluding corresponding service sectors amounted to **€87.2 billion, 4.3% higher** than in 2017.

The life science industry can be divided into three main **sub-sectors**:

- pharmaceuticals
- biotechnology
- medical devices

Of the total revenue figure cited above, 67.2% came from pharmaceuticals, 18.9% from medical devices and the remaining 13.9% from biotechnology.

If we also include corresponding service sectors, namely social and health care services, then in 2016 (the latest year for which official data are available), the total value chain recorded, according to Assolombarda, €207.5 billion in revenue and €95.5 billion in value added[(a)], and employed around 1.7 million people.

Again including corresponding service sectors, the total value added in life science is equivalent to 10% of Italy's GDP. In the region of Lombardy in particular, life science accounts for over 12% of regional GDP (and 2.7% of the national GDP), again according to Assolombarda based on 2016 data.

Lombardy has the most developed manufacturing and services cluster in the country, with €63.4 billion in revenue, over €23.5 billion in value added and 347,000 workers. These figures put Lombardy among the regional powerhouses in Europe, along with Catalonia (Spain), Baden-Württemberg (Germany) and Ile-de-France (according to Assolombarda).

The life science industry is therefore one of Italy's major manufacturing sectors. It is the sector in which high-tech businesses have attracted the most venture capital and private equity investments, with nearly €900 million invested, around 58% of the total amount invested in the sector in 2018.

The Italian life science sector features a substantial number of small, specialised businesses, which share the terrain with the major pharmaceutical groups.

a) accounting figure that measures the difference between the value of goods produced and the value of input goods and materials

HIGHLIGHTS

Overall, companies operating in the Italian life science sector have registered a moderate increase in annual revenue. They invest intensely in research and development and a very high proportion of their personnel is highly qualified.

By segment, research and development investments in Italy amounted to:

- €1.65 billion in 2018 in pharmaceuticals (+7.8% year-on-year);
- €2.26 billion in 2018 in biotechnology (+9.7%);
- €2.20 billion in 2017 (the most recent year available) in medical devices.

The sector is therefore a **dynamic ecosystem** that can respond quickly and efficiently to technological change in the market. The key areas of development within the life science sector are related to **personalised medicine and new-generation therapies**.

In recent years, life science companies have been required to invest more and more in digital technology, as the healthcare system is moving towards complete digitalisation. In digital healthcare solutions, the main areas for investment over the past few years have been:

- "Big Data"
- artificial intelligence
- genomics technology
- online platforms and telemedicine

HIGHLIGHTS

Opportunities for the sector stem from:

- rising demand from abroad, especially emerging/ developing countries
- growing demand for new technology given the progressive digitalisation of the national healthcare system
- ageing population and related illnesses are generating higher demand for drugs and medical devices
- research to develop tests that can identify the Sars-Cov -2 virus and to develop a vaccine for the virus as soon as possible (near-term opportunity)

The sector's **critical success factors** are:

- investments in R&D
- internationalisation of business, including through joint ventures and strategic partnerships abroad
- new business models and digital skills
- organisational capabilities

CONTENTS

INDUSTRY OVERVIEW

KEY CHARACTERISTICS

The Italian life science macro-sector currently contains 4,949 active companies and 155,850 employees. Total sector revenue reached **€87.2 billion in 2018, up 4.3%** from 2017. The majority of this revenue (67.2% of the total) came from the pharmaceutical sub-sector, while the medical devices and biotechnology sub-sectors accounted for 18.9% and 13.9%, respectively.

The life science sector is one of the key high-tech sectors where Italian manufacturing plays a leading role. Many companies specialise in the sector, which offers robust growth potential in support of further economic and industrial development in the country. Italian manufacturers' know-how, especially in the pharmaceutical segment where Italy is the European leader in terms of productivity, the entire sector has become very attractive to foreign investors; this bodes well for significant growth in the sector.

In fact, in 2018 **production of pharmaceutical goods** in Italy amounted to €32.2 billion, **the most of any European nation** for the second year running, ahead of Germany. Italian businesses set the **standard for global excellence** in numerous pharmaceutical product areas including biotech drugs, vaccines and advanced therapies.

The country's major manufacturing clusters in life science are, according to Assolombarda, located in Lombardy, Piedmont, Veneto, Emilia Romagna, Tuscany and Lazio. In particular, **Emilia Romagna's biomedical district in Mirandola** (province of Modena) **is the foremost biomedical district in all of Europe**.

KEY CHARACTERISTICS

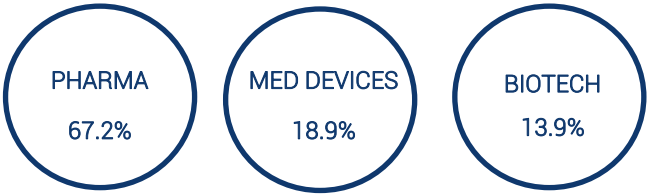
R&S AND PATENT

Vast investments are made in research and development by businesses in all three life science sub-sectors. The funds deployed for research, development and technological innovations give rise to better healthcare for citizens, enabling lifestyle improvements. They also constitute strategic investment in the national economy. In recent years, with the development of digital healthcare services, new technologies in the fields of big data and artificial intelligence are being applied to the health sector to improve all sorts of processes, from the laboratory to treatments for patient.

Patents symbolise the positive results of rigorous research activity in the medical sector. From this point of view, the life science sector is the most prolific in Italy, accounting for about 16% of all patent applications filed in 2018 (27,978 applications, 35% more than in 2009, according to the European Patent Office).

KEY FIGURES

KEY BUSINESS AREAS



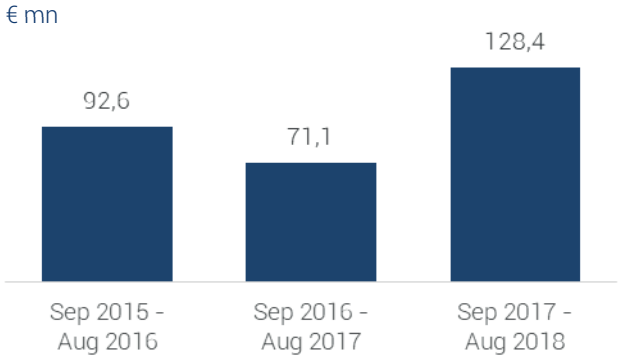
KEY CHARACTERISTICS

START-UPS

There are 496 Italian businesses registered as start-ups or innovative SMEs under economic activity codes relating to the life science sector (21.1; 26.6; 26.60.02; 26.60.09; 32.50.1; 32.50.2; 32.50.3; 32.50.4; 72.11[(a)]).

Between September 2017 and August 2018, **€128.4 million was invested in these Italian start-ups** , compared to €71.1 million over the previous 12-month period. These figures are according to Panakes, a fund launched in 2016 that specifically aims to secure investments in biomedical start-up companies. Besides Panakes, the other leading investment funds in the healthcare sector include Principia SGR, Indaco Venture Capital SGR and Innogest SGR.

LIFE SCIENCE: INVESTMENTS IN START-UPS[(b)]



a) 21.1: Manufacture of basic pharmaceutical products; 26.6: Manufacture of radiation equipment and other electric and electronic medical equipment;
26.60.02: Manufacture of electric and electronic medical equipment (including separate parts and accessories); 26.60.09: Manufacture of other radiation equipment and other electric/electronic equipment for therapeutic use; 32.50.1: Manufacture of furniture for medical use, medical devices, surgical and veterinary materials, and dental equipment; 32.50.2: Manufacture (and repair) of dental prostheses; 32.50.3: Manufacture (and repair) of orthopaedic and other prostheses; 32.50.4: Manufacture of ophthalmic lenses; 72.11: Experimental research and development in biotechnology.
b) Source: Italian Chamber of Commerce, July 2020, for ATECO categories where Chamber of Commerce information is available. It should be noted that some medical devices and biotechnology companies are registered under other categories, as they also operate in other fields, whereas pharmaceutical companies are mainly registered under 21.1 and 21.2.

KEY CHARACTERISTICS

LOMBARDY CLUSTER

The industry cluster located in the northern region of **Lombardy** comprises public and private sector entities whose work ranges from diagnostics and advanced therapies to pharmaceuticals, medical devices and applied healthcare technology. According to business association Assolombarda, the broad Italian life science sector's total **production value** was €207.5 billion in 2016 (the most recent year for which data is available), including the three main sub-sectors as well as the health and social care services sector.

Again according to Assolombarda, Lombardy is the leading Italian region in this macro-sector with a production value of €63.4 billion (again including health and social care), total value added of €23.5 billion, and roughly 347,000 employees. The life science sector makes up 10% of Italy's GDP and 12.4% of Lombardy's GDP, while the Lombard life science industry alone accounts for 2.7% of the national GDP.

The Lombard life science industry relies partly on outstanding research and innovation institutions across the country, such as leading universities and research hospitals (IRCCS). One-third of all clinical experiments conducted in Italy take place in research hospitals in Lombardy.

Finally, Lombardy is among the regional powerhouses in the pharmaceutical sector in all of Europe, along with Catalonia (Spain), Baden-Württemberg (Germany) and Île-de-France.

KEY CHARACTERISTICS

LOMBARDY CLUSTER

The regional government of Lombardy is currently funding 33 research projects, providing €114.5 million last year to the winners of a call for tenders opened in March. About 200 partner institutions are involved in these projects, 11 of which belong to the healthcare and life science sectors. More specifically, these 11 projects (listed below) will lead to the development of new drugs and innovative therapies, using predictive models and personalised diagnostic approaches for many different diseases.

- HIBAD, led by BIOREP (Milan): to employ new clinical data collection and analysis techniques in order to develop new biological markers useful for diagnostics, prognostics and monitoring activities, by setting up a regional Biological Resource Centre that will work to standardise pre-analysis procedures, the organisation of clinical data in files, as well as the treatment of biological samples (including collection, transport, handling, analysis, freezing, storage and distribution);
- SMART&TOUCH ID, led by Fondazione Don Carlo Gnocchi (Milan): to create a hub for innovative 'smart' digital rehabilitation systems connected with patients' needs, through personalised care that can be shifted from the clinic to the patient's home; this hub is also seeking to assess the effectiveness and cost-effectiveness of various care models by rigorously measuring clinical and operational outcomes;
- IMMUN-HUB, led by Milan-Bicocca University: to develop new second-generation molecules for cancer immunotherapy;
- MYEYE, led by pharmaceutical company Dompé Farmaceutici (Milano): to establish a multi-phase hub that can rapidly and effectively carry out the pre-clinical development stages of ophthalmological drugs by means of innovative platforms;

KEY CHARACTERISTICS

LOMBARDY CLUSTER

- PRINTMED-3D, led by the University of Milan: to develop and integrated platform for three-dimensional medical technologies;
- INTERSLA, led by Fondazione IRCCS – Besta Neurological Institute (Milan): to create new technological models to treat amyotrophic lateral sclerosis (ALS);
- INSpIRIT, led by the National Oncological Androtherapy Centre (Pavia): to develop new radiotherapy approaches, which consist in devising an innovative light source that can produce new ions such as oxygen, helium and lithium;
- PAIN RELife, led by the European Institute of Oncology (Milan): to establish an ecologically sustainable hub to treat patients in pain: the entire healthcare chain is involved in this project, from diagnosis to home therapy, including remote monitoring and patient/caregiver empowerment practices;
- DSF (Digital Smart Fluidics), led by Fluid-O-Tech (Milan): to build a standardised fluidics platform upon which 'smart' biomedical devices can be developed for both in-hospital and home infusion in the fields of inpatient therapy, artificial nutrition, pain relief and resuscitation;
- RE-HUB-ILITY, led by ICS Maugeri (Pavia): to build an integrated platform that brings together healthcare operators, caregivers, patients and information technology, in order to devise and carry out home treatment plans that can be monitored remotely;
- NEWMED, led by the Milan Polytechnic University: to develop innovative methods and materials for personalised precision medicine.

KEY CHARACTERISTICS

LOMBARDY CLUSTER

LIFE SCIENCE: PROJECTS FUNDED BY THE REGION OF LOMBARDY IN THE 2019 RESEARCH & INNOVATION HUB TENDER
(amounts in euros)

PROJECT	VALUE OF PROJECT	FUNDING
HIBAD	5.499.681,90	2.563.844,00
SMART&TOUCH ID	6.647.699,00	2.914.253,54
IMMUN-HUB	9.490.337,14	4.167.588,50
MYEYE	7.218.950,00	3.265.320,00
PRINTMED-3D	7.272.719,43	3.163.089,29
INTERSLA	954.689,57	4.166.832,65
INSPIRIT	9.916.695,00	3.812.578,00
PAIN RELIFE	5.340.117,51	2.701.025,79
DSF: DIGITAL SMART FLUIDICS	7.715.695,91	3.326.178,36
RE-HUB-ILITY	7.793.767,21	3.817.354,20
NEWMED	6.638.705,61	3.015.786,43

Source: Open Innovation Regione Lombardia

KEY CHARACTERISTICS

LATIUM CLUSTER

According to the latest data published by Assolombarda (for 2016), life science sector production value in the central Italian region of Lazio came to €26.8 billion, including corresponding service sectors.

The Cluster of Health Innovation and Community (CHICO), Lazio's first official healthcare cluster, is a privately-owned non-profit organisation that operates in both life sciences and health care on an international scale. This cluster includes:

- local government health service agencies
- universities
- other research institutes
- hospitals
- corporations active in pharmaceuticals, the biomedical industry, ICT, functional nutrition and the agri-food industry.

In 2017, at the "Meet in Italy for Life Science" conference in Turin, this cluster unveiled a project called LifeSeeder, a crowdfunding initiative as a new means of procuring investments in SMEs in the sector. More specifically, LifeSeeder will put SMEs and potential new investors in contact, with a focus on equity crowdfunding in the life science industry, so that investment funds, large businesses and venture capitalists can find and select the best SMEs and start-ups active in the sector. The initiative's main goal is therefore to create guidelines for further development in the life science sector, both within the region and across the country.

Another initiative through which CHICO is promoting development in the sector is called Synergy: it is a forum where members of the cluster can present other members their offers or requests regarding financial partnerships, commercial deals or R&D activities.

KEY CHARACTERISTICS

LATIUM
CLUSTER

The cluster currently has 130 members; combined, these institutions have annual revenue of €7 billion and around 15,000 employees.

In June 2020, equity crowdfunding business Lifeseeder signed an agreement with CHICO cluster member Zcube and Zambon Research Venture, a well-known division of the Zambon group that is active in life science innovation projects. The purpose of this deal is for these ventures to cooperate in synergy on life science investment projects, notably the 2020 edition of Open Accelerator for a start-up and research team looking to develop digital solutions to human health problems.

The global Bio Digital Convention was held (online, for the first time ever) from 8th to 12th June 2020, and both the CHICO cluster and the Region of Lombardy were among the participants. This is considered the most important life science sector event in the world; it aims to bring about investment opportunities, along with technological and business partnerships in all strategic life science fields such as bio-computing, genomics and genetics, medical equipment, cellular biology, nanotechnology, stem cell research, pharmaceuticals and drug delivery methods.

KEY CHARACTERISTICS

EMILIA-ROMAGNA CLUSTER

Life science sector production value (including health and social care) in the north-central region of Emilia Romagna came to €15.3 billion in 2016, again according to Assolombarda.

Clust-ER Health, an association officially recognised by the Emilia Romagna regional government, encompasses numerous businesses (large, medium and small), healthcare facilities as well as education and training providers. All of these institutions share skills, ideas and resources in an effort to boost the competitiveness of Emilia Romagna's healthcare sector. Clust-ER is coordinated by ASTER, a cooperative company based in Emiia Romagna that promotes innovation and technology transfer.

Emilia Romagna is in fact considered to be at the forefront of the healthcare industry on a national level, with a number of large companies active in pharmaceuticals and in emergent technological niches in the medical sector, such as regenerative medicine. For these reasons, the regional government believes the medical sector is a crucial component for the region's economic development in general.

KEY CHARACTERISTICS

EMILIA-ROMAGNA CLUSTER

The healthcare industry in Emilia Romagna is comprised of around 700 businesses with about 14,000 employees combined.

This regional cluster is active in four main areas:

- new generation biomedicine and prosthetics
- regenerative and reparative medicine
- pharmaceuticals and molecular biology
- technology for a healthy, active and independent lifestyle

Of particular importance in Emilia Romagna is the Mirandola biomedical district. In and around this small town north of Modena, one of the largest biomedical districts in the world, with over one hundred companies that specialise in producing dialysis equipment, cardiac surgery equipment and instruments, blood transfusion equipment and other medical devices. Most of these companies are located within the municipalities of Mirandola, Carpi and Novi di Modena. Between manufacturers and related service businesses, this district employs around 5,000 people.

Through ASTER, the Emilia Romagna region participates in the European Life Science Ecosystems (ELISE) project, which promotes business investments in research and innovation to develop links and synergies between them. In particular, ELISE promotes investments in product and service development, technology transfer and social innovation. It is a five-year project (from 1st January 2017 to 31st December 2021) running at a cost of €1,355,000.

KEY CHARACTERISTICS

TUSCANY CLUSTER

The Tuscan life science sector, including corresponding services, had an estimated total production value of €14.5 billion in 2016 according to Assolombarda.

The **Toscana Life Science (TLS) Cluster,** in operation since 2005 and based in Siena, brings together all public and private sector entities engaged in biotechnology, pharmaceuticals, nutraceuticals, cosmeceuticals, medical devices and ICT applications for life sciences.

This district is specifically composed of:

- companies (start-ups, spin-offs, SMEs and major pharmaceutical industry players);
- high schools;
- institutes belonging to the CNR (National Research Council);
- Tuscan universities;
- university-based hospitals;
- local healthcare agencies;
- foundations, service centres and both public and private research institutes.

KEY CHARACTERISTICS

TUSCANY CLUSTER

Some key numbers for the TLS cluster as at 31/12/2019 are:

- 386 employees
- 509 publications, 84 of which were released in 2019
- 405 partnerships and licence agreements
- 52 patents

- €211 million in funds generated and financing obtained
- €17 million in revenue earned by affiliated businesses and research institutes
- €3.2 million in income from activities and services provided by TLS itself

The cluster's objectives are to: facilitate the process of starting up a business in the biotechnology field applied to healthcare; support research in orphan illnesses; manage technology transfers in biomedicine and enhance the value of research performed in the region through national and international networking activities.

One of the more notable projects recently completed by the cluster was OMVac, which was carried out as part of the EU's 7th Framework Programme. This initiative brought in €2.61 million in funding over five years, for the application of synthetic biology technology to develop new bacterial strains in order to produce new vaccines.

KEY CHARACTERISTICS

In Piedmont, the life science sector including corresponding services had a total production value of €12.2 billion in 2016 according to Assolombarda.

Piedmont's healthcare and life sciences innovation cluster is called **BioPmed**. It originated from the region's aspiration to connect businesses, research centres, universities, foundations, local health services and hospitals, with a view to stimulating investments, innovation and internationalisation processes in the fields of human health and life sciences. BioPmed's goal is to form a dynamic and competitive life science sector cluster that interacts effectively with the healthcare system and that gains national and international recognition.

This cluster is made up of around 400 entities, including businesses, research centres, universities and foundations, and has achieved the following:

- more than 20 strategic international cooperation agreements
- 60 R&D projects
- €25 million in financing for healthcare and life science programmes
- 16 EU-level projects activated
- 3 major B2B events organised: EuroMedTech, BioEurope and Meet in Italy for Life Science

KEY CHARACTERISTICS

In particular, the fourth edition of the "Meet in Italy for Life Science" international conference was held in Turin in 2017. Participants included around 400 operators from 36 different countries. The sixth and most recent edition of this event was held in 2019 in Trieste, while the 2020 edition was postponed due to Covid-19; it has now been re-scheduled for the 12th to 14th May 2021 in Genoa.

S3MARTMED – European medical technology investment cluster: the S3martMed project's goal is to modernise the S3 medical technology platform. With five partner clusters – Lyonbiopole (Auvergne Rhône-Alpes, France), BioWin (Wallonia, Belgium), GAPR Medsilesia (Upper Silesia, Poland) and Bioregion STERN (Baden-Württemberg, Germany) along with BioPmed of Piedmont – the idea is to form a pan-European medical cluster focused on cooperation between regions and between sectors. The cluster seeks to offer investment and partnership opportunities for SMEs, technology centres and other regional cluster stakeholders. The ultimate goal of S3martMed is then to support entreprenurial partnerships until they become mature relationships, by working out investment and funding scenarios with regional authorities.

MAGIA - **Medtech Alliance for Global Internationalization**: part of the EU's COSME programme, MAGIA is an alliance between four key clusters: BioPmed, BioWin, Lyonbiopole and Life Science Nord of Hamburg, Germany. The purpose of MAGIA is to increase the visibility of SMES operating in the medical sector and thus attract investors to them. The medical technology sector is considered the most promising of the emerging sectors covered by the alliance.

KEY CHARACTERISTICS

According to Assolombarda data for 2016, the production value of the life science sector in the Veneto region was €14 billion.

OTHER CLUSTERS AND ENTITIES

In addition to the main regional clusters described in the last few slides, which constitute the sector's largest manufacturing districts, there are numerous other significant regional healthcare institutions, with the most noteworthy being: Friuli Venezia Giulia's Molecular Biomedicine Consortium, the Sardinia Research Consortium, the Bioscience Technology District of Campania, the Human Health and Biotechnology District of Puglia, the Micro- and Nanotechnology Systems District of Sicily, the Vita Liguria Science District, and the BioTecnoMed Cooperative of Calabria.

The main Italian **business industry associations** within the life science sector are:

- Farmindustria (pharmaceuticals)
- Federchimica-Assobiotech (chemicals and biotechnology)
- Confindustria Dispositivi Medici (medical devices)

Italy's leading **research institutes** are:

- CNR: the National Research Council
- ENEA: the National Agency for New Technology, Energy and Sustainable Development
- IIT: Italian Institute of Technology
- ISS: Istituto Superiore di Sanità (the leading scientific body of the Italian national healthcare system)

KEY CHARACTERISTICS

ALISEI CLUSTER

- ALISEI is a nationwide life sciences technology cluster that delineates three-year action plans to:
- facilitate innovation, research, development and technology transfers in the life science sector across the country;
- attract public and private sector funding to develop and implement innovative projects in the field;
- promote and provide incentives for innovation in the medical sector.

The current ALISEI action plan consists of three sections:

- Identify key technological roadmaps for life science sector development. The aim here is to pinpoint priority areas for innovation; the most recent areas identified are e-health, advanced and non-invasive diagnostics, biotechnology, biocomputing and pharmaceuticals, regenerative, predictive and personalised medicine, nutraceuticals, nutrigenomics and functional nutrition, technology for active ageing and in-home nursing care.
- Advance a working programme for the cluster, along with the specific actions to be undertaken in pursuit of the technological roadmaps.
- Draft working plans for recovery and development of the sector in the South of Italy.

On 16th January 2020, the ALISEI cluster and ITA - Italian Trade Agency (ITA - Italian Trade Agency is the Governmental agency that supports the business development of our companies abroad and promotes the attraction of foreign investment in Italy) signed an agreement to promote the Italian life science sector. This is a two-year plan to create new opportunities for life science companies and make the sector more attractive to foreign investors. In addition, ALISEI and ITA—Italian Trade Agency have committed to attending national and international events that can boost the cluster's value. The major events identified are: a JP Morgan event in San Francisco (13-16 January 2020), the Bio Intenational Convention in San Diego (8-11 June 2020); Meet in Italy for Life Science in Genoa (originally scheduled for 14-16 October 2020, but postponed to 12-14 May 2021 due to Covid-19), and BIO Japan Pacific in Yokohama (14-16 October 2020).

KEY SECTOR DATA

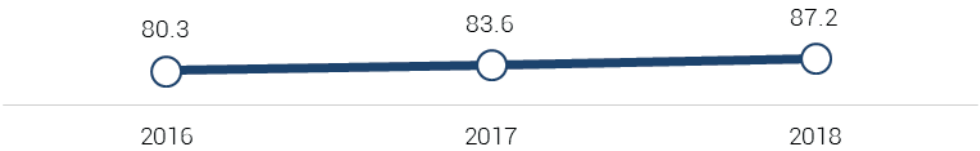
QUANTIFYING THE ITALIAN LIFE SCIENCE SECTOR: REVENUE

In 2018, **life science macro-sector revenue** (pharmaceuticals, biotechnology and medical devices) totalled **€87.2 billion**, **4.3%** higher than in 2017. The pharmaceutical sub-sector generates the majority of revenue (67.2% in 2018), while medical devices accounted for 18.9% and biotechnology the remaining 13.9% of the total.

Life science remains one of the most important high-tech sectors in terms of Italian manufacturing specialisation. It is a sector that is highly inclined towards exports and internationalisation. In the pharmaceutical sector in particular, Italy is at the forefront of the industry: Italy claimed the highest pharmaceutical production value in Europe in 2018, having overtaken Germany and far ahead of France, the United Kingdom and Spain.

LIFE SCIENCE: TOTAL REVENUE (PHARMACEUTICAL, MEDICAL DEVICES AND BIOTECHNOLOGY SUB-SECTORS), 2016-2018

€ bn



Source: Cerved Group illustration of Farmindustria, Federchimica Assobiotech and Confindustria Dispositivi Medici data

KEY SECTOR DATA

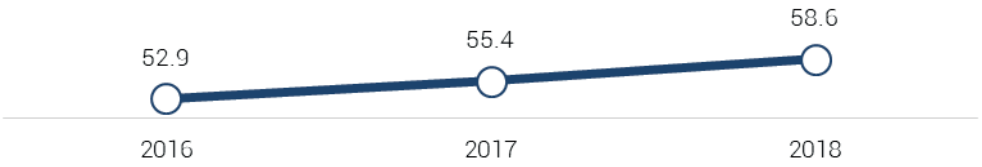
THE PHARMACEUTICAL SEGMENT

Revenue in the pharmaceutical segment reached €58.6 billion in 2018, a 5.8% increase from the 2017 figure, which was in turn 4.7% higher than the previous year. The Italian pharmaceutical industry consolidated its position as the leading EU pharmaceutical producer. Drugs manufactured in Italy amounted to €32.2 billion in 2018 (compared to €31.2 billion in 2017); after many years as the closest 'follower' to Germany, Italy became the top producer in 2017. Over the last ten years, according to the national industry association Farmindustria, Italian pharmaceutical production has risen by 100% thanks to a boom in exports. In fact, in 2018 exports of Italian-made pharmaceuticals rose by 4.7% year-on-year to €25.9 billion, covering 80.4% of the total production value.

Imports of pharmaceuticals in 2018 amounted to €26.4 billion, rising by 9.1% from the 2017 figure, which in turn was 5.7% above the previous year's total.

AGGREGATE REVENUE OF PHARMACEUTICAL COMPANIES, 2016-2018

€ bn



Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

There are **291 pharmaceutical businesses** that operate in Italy, of which:

- 77% specialise in the manufacture of **medicines**;
- 23% produce **input materials for pharmaceuticals**.

Total pharmaceutical sector employment was around 66,500 people in 2018, 1.7% more than in 2017.

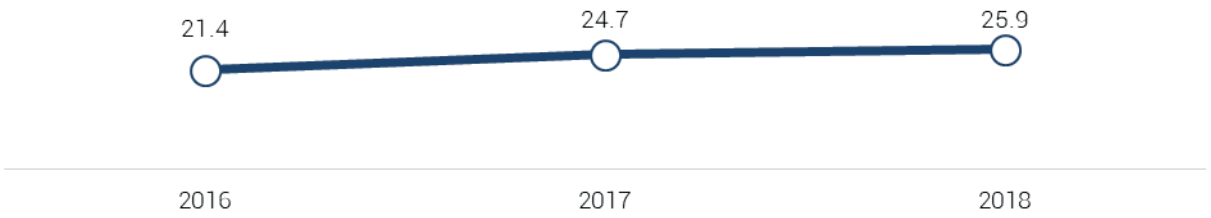
As mentioned above, the **growth in Italian pharmaceutical production has been driven by exports**: the value of exports rose by 4.7% year-on-year to €25.9 billion in 2018; €16.6 billion (or 64.1% of the total) were medicines. The majority of exports of Italian products are to other European countries (69.9%, or 56.8% to the EU-28 only); of the other continents, the Americas account for 17.7% of Italian pharmaceutical exports and Asia, a growing market, accounts for 10% of the total. By individual country, the leading export destinations are Belgium (15.2% of total exports), the United States (14.4%), Switzerland (10.9%), Germany (10.7%) and France (7.3%).

Imports reached €26.4 billion in 2018, a 9.1% increase from 2017, with imported medicines alone worth €13.9 billion. Most imported drugs come from other European countries (82.2%), followed by the Americas (13.9%). By individual country, Italy imports most from Germany (17.4% of the total), Belgium (15.8%), the United States (13.6%), Switzerland (11.6%) and France (10%).

KEY SECTOR DATA

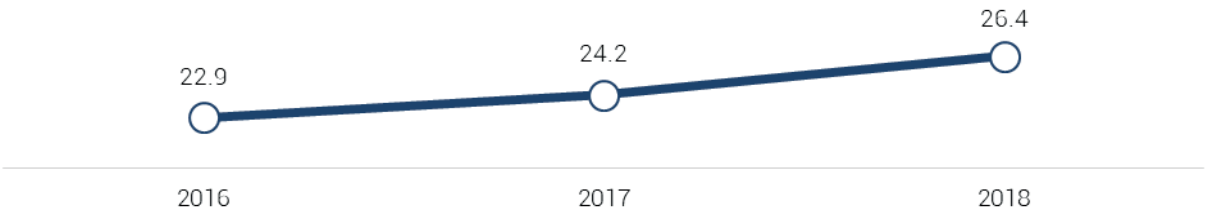
VALUE OF PHARMACEUTICAL EXPORTS, 2016-2018

€ bn



VALUE OF PHARMACEUTICAL IMPORTS, 2016-2018

€ bn



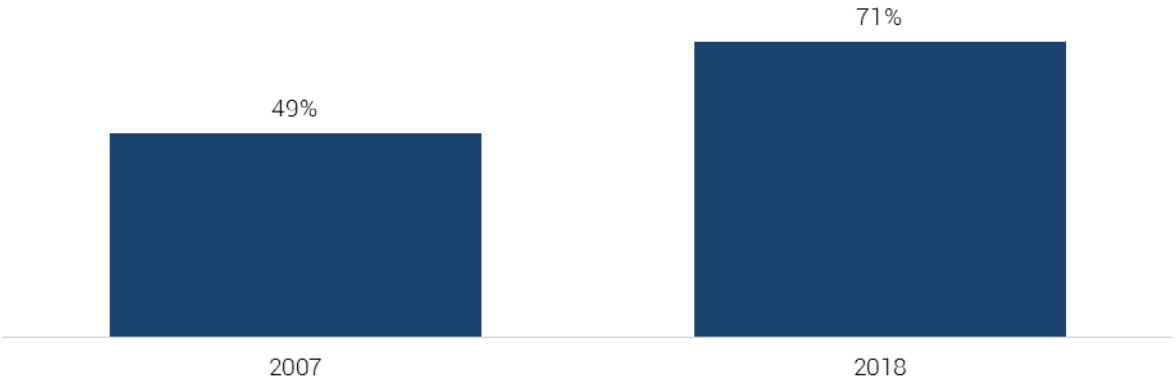
Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

Exports therefore make up a substantial portion of Italian companies' sales. Indeed, Italian-owned pharmaceutical corporations generate over 70% of their annual revenue from exports on average, and among foreign-owned corporations operating in Italy, that figure rises to a massive 90%. Sales abroad by Italian-owned corporations have grown from €3.1 billion in 2007 to €7.5 billion in 2018.

ITALIAN-OWNED PHARMACEUTICAL COMPANIES' SALES ABROAD, 2007 AND 2018

%



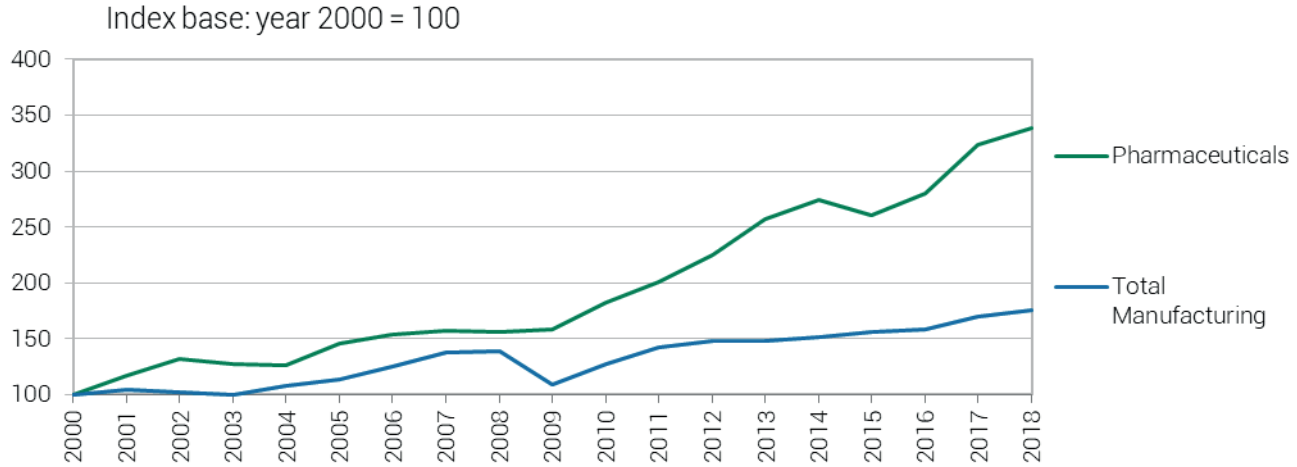
Source: Cerved Group illustration of Farmindustria data

Italy is also first in Europe in terms of contract development and manufacturing organisations (CDMO). These are businesses that produce drugs as contractors for other firms. The rise of CDMOs in Italy has been driven by growing foreign demand. Exports of contract manufactured goods from Italy reached €1.9 billion in 2017 (the latest year for which such data is available), ahead of Germany (€1.7 billion) and France (€1.5 billion).

KEY SECTOR DATA

Again, the pharmaceutical export value was €25.9 billion in 2018, up from €24.7 billion in 2017. The graph below shows how Italy's pharmaceutical exports have been growing faster than overall manufacturing exports for quite a few years.

PHARMACEUTICAL EXPORT TREND COMPARED TO OVERALL MANUFACTURING EXPORT TREND, 2000-2018



Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

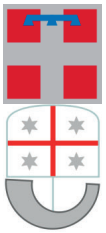
Most drugs produced in Italy are manufactured in the following five regions: Lombardy, Lazio, Tuscana, Emilia Romagna and Veneto. These five account for almost 90% of the sector's jobs. However, there are pharmaceutical companies based in other regions that generate value. The notable production regions are:

LOMBARDY:

29,000 direct workers
22,000 service workers
#1 pharma region in Europe

VENETO:

Over 3,000 direct workers
9,000 service workers
30% high-tech exports



PIEDMONT & LIGURIA:

2,100 direct workers
9,100 service workers

EMILIA ROMAGNA:

3,800 direct workers
8,500 service workers
Excellent service sector cluster

MARCHE:

3,400 direct+service workers
Exports to 40+ countries from Ancona

TUSCANY:

7,000 direct workers
5,400 service workers
Top-10 high-tech cluster

LATIUM:

16,300 direct workers
7,400 service workers
83% of exports are high-tech

ABRUZZO:

1.500 direct workers (100 in R&S)
1.600 service workers

CAMPANIA:

Over 9,000 direct workers
4,000 service workers

PUGLIA:

Hosts excellence centres of some major foreign multination-als

SICILY:

1,000 direct workers
3,000 service workers

Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

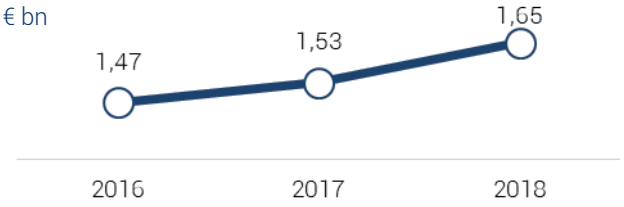
R&D

R&D investments in the sub-sector **grew by 7.8%** year-on-year to **€1.65 billion** in 2018. This spending is equivalent to **7% of total R&D spending in Italy**, putting pharmaceuticals in third place for the value of research investments. The number of employees engaged in R&D work was around 6,600, up 3% year-on-year, and 52% of these employees are women.

There is a significantly **higher concentration of innovative businesses** in pharmaceutical sector than in the manufacturing sector overall. A substantial portion of R&D investments go towards **clinical trials**, to the tune of €700 million per year; this is about 20% of the total amount spent to conduct clinical trials in the entire EU.

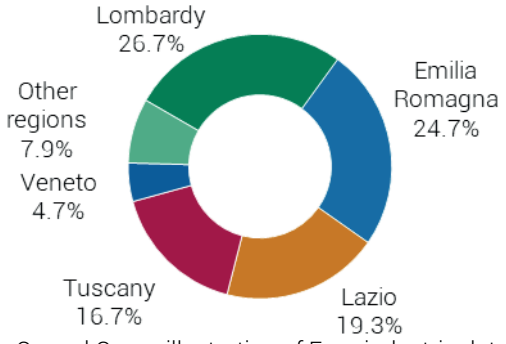
In terms of the amount spent on research and development, **Lombardy is the number one region in Italy**, followed by Emilia Romagna, Lazio, Tuscany and Veneto. Other regions where businesses invest in pharmaceuticals are Abruzzo, Piedmont, Campania, Sicily, Friuli Venezia Giulia, Trentino Altro Adige and Marche.

PHARMACEUTICAL INDUSTRY R&D INVESTMENTS, 2016-2018



PHARMACEUTICAL INDUSTRY R&D INVESTMENTS BY REGION, 2018

2018: 100% = €1.65 bn



Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

In a nutshell, the Italian pharmaceutical industry is:

- the **manufacturing sector with the highest growth rate**: +22% from 2008 to 2018, vs. -14% in manufacturing overall;
- the manufacturing sector with the **highest export growth rate**: +117% from 2008 to 2018, vs. a +27% average among the major Italian industrial sectors;
- the **fastest-growing sector in the country for employment**: +8.6% from 2014 to 2018, vs. +2% manufacturing sector average (there are now 4,500 more pharma sector employees than in 2014, mostly related to R&D positions; 42% of the 66,500 workers in the sector are women and 81% of newly hired employees are under 35 years old;
- the **third-leading sector in Italy for R&D investments**, accounting for 7% of total national R&D spending, with particularly advanced research ongoing in the following fields: haemoglobin derivatives, vaccines, rare diseases and advanced therapies (Italy is the EU leader in this last field);
- **one of the 'greenest' sectors** of the economy, having reduced energy consumption by 54% and greenhouse gas emissions by 74% over the last decade;
- compared to other EU countries' pharmaceutical sectors…
  - **1st in production value** (€32.2 billion in 2018);
  - **1st in export growth** (+117% vs. +81% EU average from 2008 to 2018);
  - **1st in R&D investment growth** (+35% vs. +20% EU average since 2013).

Source: Cerved Group illustration of Farmindustria data

KEY SECTOR DATA

THE MEDICAL DEVICES SEGMENT

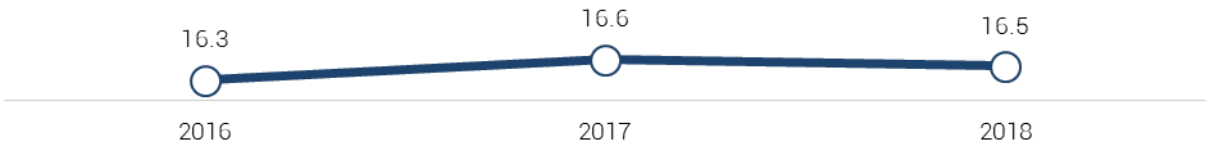
The Italian medical devices sector generated €16.5 billion in revenue in 2018, of which €5.1 billion in foreign sales, broadly stable from the previous year (-0.4%) after a 1.7% increase from 2016 to 2017.

This is a very diverse sector that is highly **innovative and specialised**, with a leading role played by major foreign multinationals that are present in the sector across the globe.

Exports account for 30.9% of the total 2018 revenue figure cited above (€5.1 billion, up 4.7% from 2017), whereas the domestic market value was €11.4 billion (-1.7% year-on-year).

AGGREGATE REVENUE OF MEDICAL DEVICE COMPANIES, 2016-2018

€ bn



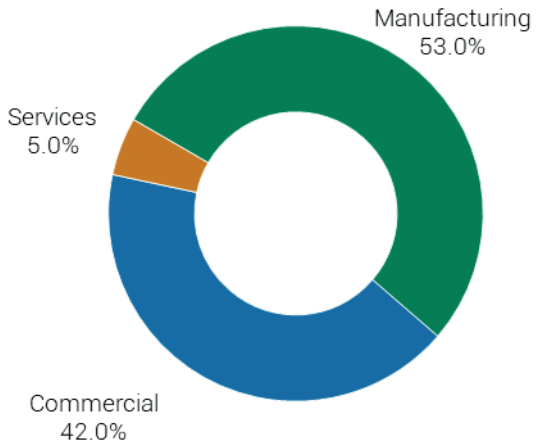
Source: Cerved Group illustration of Confindustria Dispositivi Medici data

KEY SECTOR DATA

The medical devices sector includes electrical and electronic medical equipment, in-vitro diagnostics instruments, e-health devices and any other devices used to diagnose, evaluate or monitor patients affected by an illness, injury or other medical condition. The medical devices sub-sector has 3,957 active companies, of which around 2,100 are manufacturers.

NUMBER OF MEDICAL DEVICE COMPANIES BY TYPE OF BUSINESS, 2018

2018: 100% = 3.957



Source: Cerved Group illustration of Confindustria Dispositivi Medici data

KEY SECTOR DATA

About 5% of Italian medical device businesses are large companies, meaning that the vast majority are **specialised SMEs**. The sector employs a total of 76,400 people, many of whom have highly specialised qualifications.

Sales abroad have been growing for eight consecutive years, and rose by 4.7% from 2017 to 2018. The key destination countries are the USA, France and Germany (in that order). Italy is the 12th biggest exporter of medical devices in the world. Imports are also on the rise (+3.4% year-on-year in 2018), and the leading countries of origin are (in order) Germany, the Netherlands and Belgium.

The Italian market for medical devices amounted to €11.4 billion in 2018, 66% of which is related to the public healthcare system, and the remaining 34% private-sector healthcare institutions.

MEDICAL DEVICES REVENUE BREAKDOWN BY DISTRIBUTION CHANNEL, 2018

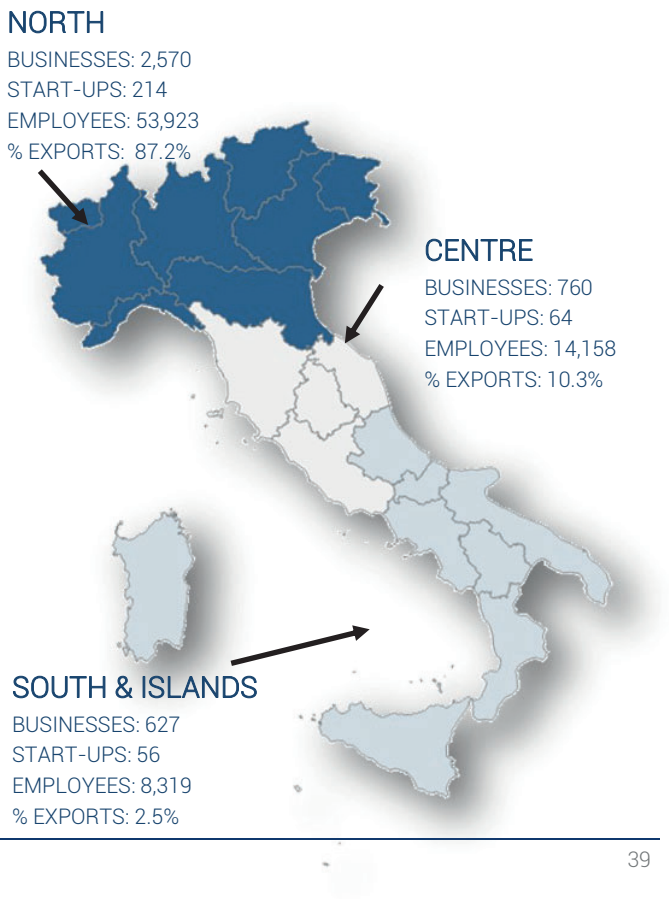
2018: 100% = €11.4 bn

Source: Cerved Group illustration of Confindustria Dispositivi Medici data

KEY SECTOR DATA

REGIONAL DISTRIBUTION OF 2018 DATA

The portion of the country that represents the lion's share of the sector is the North. The region of Lombardy alone contains 1,213 medical device businesses (including 73 start-ups) and 24,234 employees. Lombard exports take up 28.2% of the national export value. Another major role in northern Italy is played by Mirandola in Emilia Romagna, the largest biomedical district in Europe.



Source: Cerved Group illustration of Confindustria Dispositivi Medici data

KEY SECTOR DATA

R&D

Investments in research and development in the medical devices sub-sector amounted to €2.2 billion in 2017, the most recent data available. The personnel count for R&D activities in the country is 9,168, or about 12% of the total in the sector. R&D is carried out by medical device companies in order to design new machines that integrate advanced digital software.

With the national healthcare system undergoing a reorganisation process for sustainability, digital innovations are likely to shape the future of the healthcare sector. The digital innovation factor is speeding up changes and leading to improvements in patient personalisation, monitoring, continuity of treatment and access to treatment, which should ensure a more effective and efficient healthcare system.

The enormous potential for improvements stemming from digitalisation could subsequently be extended to other areas. For instance, a single piece of medical equipment could be used to conduct several tests simultaneously, could be used to provide suggested diagnoses to practitioners and/or recommend further analyses or complementary tests.

According to industry association Confindustria Dispositivi Medici, as of 2018 there were 334 **start-ups** active in the medical devices sector in Italy, about 40% of which are innovative SMEs, and 43% are spin-offs of public sector research programmes. The main segment on which these recently founded companies are focusing is diagnostics (38% of the total), followed by rehabilitation (12%) and oncology (11%).

KEY SECTOR DATA

THE BIOTECHNOLOGY SEGMENT

In 2018, revenue in the biotech sector came to €12.1 billion, 4.3% higher than in 2017, after 4.5% growth from 2016 to 2017. The number of companies operating in the sector remained broadly stable last year, going from 701 in 2018 to 696 in 2019; these companies employed 13,313 in 2019, compared to 12,950 in 2018.

Research and development activity is considerable and growing in all areas of this sub-sector. Total R&D investments reached €2.26 billion in 2018, up 9.7% from 2017 and 25% more than in 2014. The core business area for 49.4% of Italian biotech companies is related to human health.

AGGREGATE REVENUE OF BIOTECHNOLOGY COMPANIES, 2016-2018

€ bn

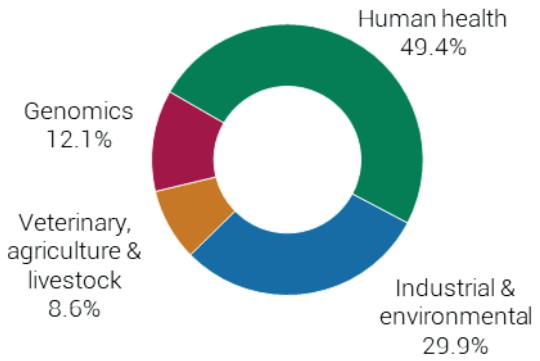
Source: Elaborazione Cerved Group su dati Federchimica-Assobiotech

KEY SECTOR DATA

The business most commonly practiced by Italian biotech companies is human health (49%), followed by services and products for industrial and environmental applications (29.9%).

NUMBER OF BIOTECHNOLOGY COMPANIES BY BUSINESS SEGMENT, 2019

2019: 100% = 696



Source: Elaborazione Cerved Group su dati Federchimica-Assobiotech

Two-thirds of the national biotech industry's revenue is generated by foreign-owned companies, which are active especially in human health. Italian-owned companies, accounting for the majority in terms of the number of active biotech companies, tend to be smaller in scale but do generate about half of the overall sales in the products/services for industry and the environment segment.

In 2019, according to industry association Assobiotech, there were 696 active companies in the sector, including:

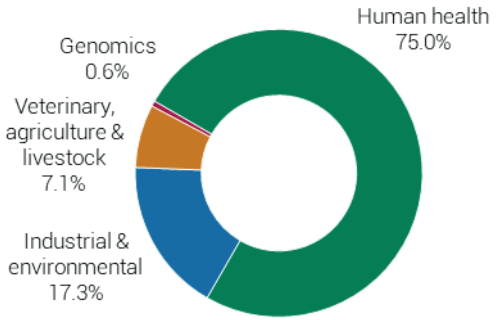
- 344 in **human health** (biopharmaceuticals, diagnostics and vaccines)
- 208 in products and services for industrial and environmental applications – these companies generally offer solutions to improve manufacturing process sustainability;
- 84 in the genomics, proteomics and enabling technologies segment – they conduct fundamental research for all main fields of application for biotechnology;
- 60 in biotechnology for veterinary, agricultural and animal husbandry applications – they develop products for food security and animal nutrition.

KEY SECTOR DATA

The **human health** segment accounted for **75% of biotech sector revenue**, or €9.1 billion, in 2018, and was the focus of over 83% of the sector's total R&D expenditures.

BIOTECHNOLOGY SECTOR REVENUE BY SEGMENT, 2018

2018: 100% = €12.1 bn



Source: Cerved Group illustration of Federchimica-Assobiotech data

Another notable characteristic is that nearly all of the country's biotech operations take place in north-central Italy, accounting for 98.3% of sector revenue.

Within the human health segment, Italy boasts a superior position in the field of advanced therapies, including **somatic cellular therapy, gene therapy and regenerative medicine**.

START-UPS

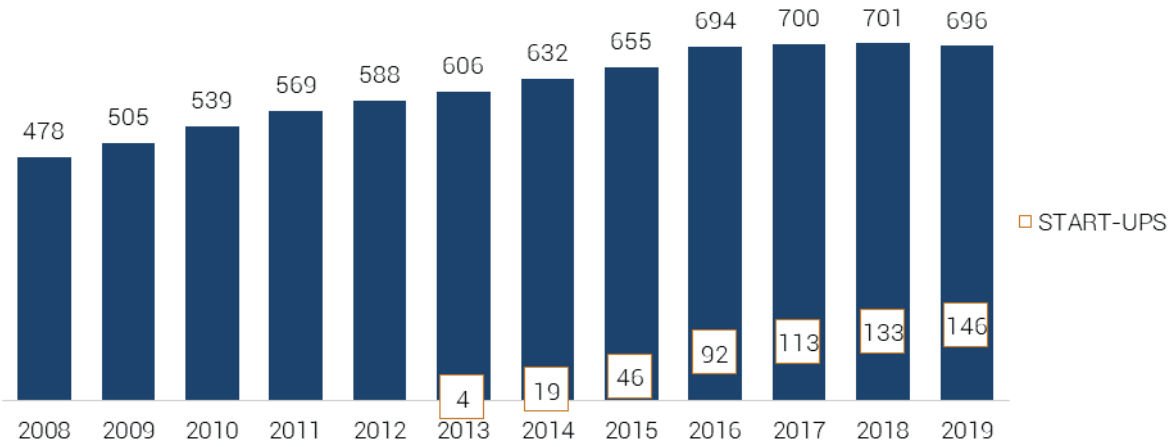
Start-ups and innovative SMEs make up 20% of the Italian biotech business population. According to Assobiotech, over 50 new innovative start-ups active in biotechnology have registered in Italy.

KEY SECTOR DATA

TREND IN THE NUMBER OF BUSINESSES

Over the last ten years, the number of biotech businesses has risen consistently. Because biotechnology activities are spread across several different official ATECO economic activity categories, it is impossible to provide precise figures from business registry data alone. However, Assobiotech claims that there were 696 companies active in 2019, compared with 701 in 2018, with 146 start-ups as of 2019 compared to 133 the year before.

NUMBER OF BIOTECHNOLOGY START-UPS, 2008-2019



Source: Cerved Group illustration of Federchimica-Assobiotech data

KEY SECTOR DATA

R&D

Total R&D investments made by biotech companies amounted to €2.26 billion in 2018, 9.7% more than in 2017, with €770 million specifically going towards research projects.

83.3% of the total R&D spending in the sub-sector stemmed from companies active in the human health segment.

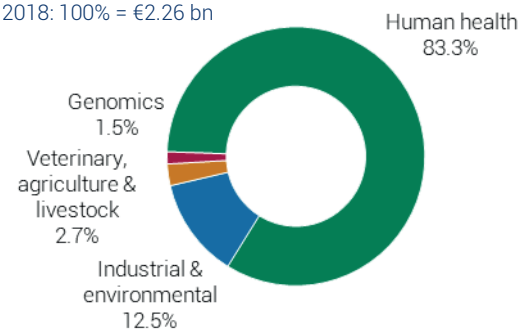
Italian biotech companies are investing heavily in research into diseases and illnesses for which no cure or definitive therapy has yet been found. They are concentrating especially on developing cancer treatments. However, over the last two years more experiments have been done in infectious diseases, and this trend is currently ramping up in the race to develop a vaccine against the Sars-Cov-2 virus.

R&D investments in biotechnology in Italy, according to Assobiotech, make up 3.4% of all R&D spending by producers in the country; this figure is impressive considering that the number of biotech businesses is only 0.2% of the total in Italy.

These investments take place almost entirely in just three regions of northern and central Italy: Lombardy (45.3%), Lazio (22.4%) and Tuscany (29%).

BIOTECHNOLOGY INDUSTRY R&D INVESTMENTS, 2016-2018

BIOTECHNOLOGY INDUSTRY R&D INVESTMENTS BY SEGMENT, 2018



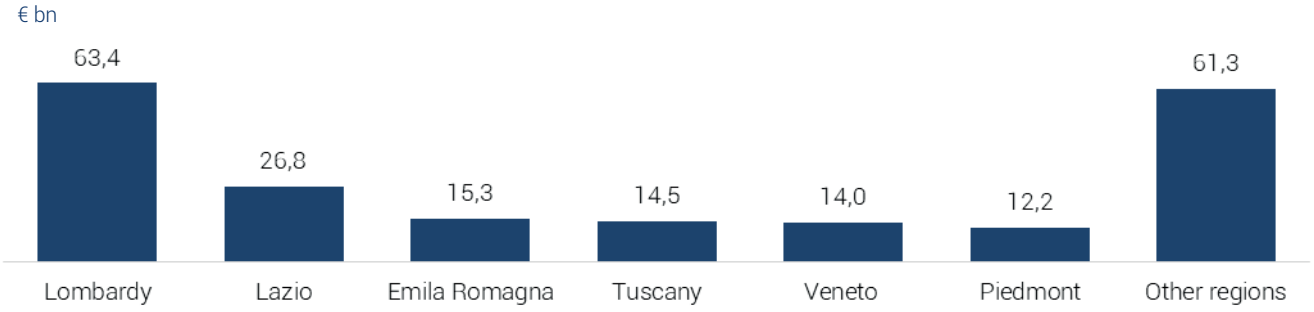
Source: Cerved Group illustration of Federchimica-Assobiotech data

KEY SECTOR DATA

OVERVIEW OF THE LIFE SCIENCE SECTOR INCLUDING CORRESPONDING SERVICE SECTORS

Beyond the three manufacturing sub-sectors covered above (pharma, biotech and medical devices), the full life science **value chain** can be considered as including all companies and institutions that provide **health and social care services**: public and private hospitals, specialised clinics and medical practices, as well as healthcare service agencies. When the full value chain is included, according to Assolombarda, in 1016 the life science sector had total revenue of €207.5 billion, and value added of €95.5 billion. **Lombardy** is the Italian region with the most extensively developed life science chain, with a production value of €63.4 billion and value added of over €23.5 billion.

LIFE SCIENCE PRODUCTION VALUE, INCLUDING CORRESPONDING SERVICE SECTORS, BY REGION, 2016



Source: Cerved Group illustration of Assolombarda data

MAIN TRENDS

MAIN TRENDS IN TECHNOLOGY AND INNOVATION

There is an ongoing process of technological development in which leading scientists and technology experts are making progress towards a digitally equipped world that should be beneficial to society as a whole. **Digital health** is an integral part of this process: the aim is to enhance digital systems in the healthcare sector in order to make healthcare more accessible to all and to improve the economic sustainability of the national healthcare system.

The **Italian digital healthcare market value** is estimated at €1.7 billion as of 2018, up 4.2% from the previous year, according to daily financial newspaper *Il Sole 24 Ore*.

The key technological trends are digitalisation and automation. Enhancing healthcare services through digital technology and tools such as big data and artificial intelligence will enable the collection, tracking and processing of vast quantities of data in a much faster and more efficient manner than ever before. Digital innovations are thus revolutionising the dynamics of the sector, from the laboratory to the production line to the point of patient care.

MAIN TRENDS

The main areas in which digital technology is coming into contact with the health sector are:

- "Big Data"
- artificial intelligence
- genomics technology
- online platforms and telemedicine

BIG DATA

The healthcare sector generates a huge amount of data and information, relating not only to diagnoses, prescribed therapies, images and test results, but also invoices and receipts for healthcare services and other administrative records. For each patient there is a sizeable quantity of data, creating a virtually immeasurable quantity for the healthcare system as a whole to handle. With big data solutions, it can all be processed and examined promptly.

Big data can be used to help practitioners diagnose patients more quickly and accurately, as well as enable them to search through millions of medical files in order to inform analyses on specific patient samples and thus implement preventive medicine strategies, something that until very recently was seemingly unimaginable due to the dispersion of information in the national healthcare system.

This sprouting big data revolution has thus far been applied concretely in the form of:

- electronic healthcare folders
- healthcare files
- individual electronic hospital/medical charts and records
- patient notebooks

The Pain-RELife project, one of the 33 funded by Lombardy's regional government through the Research and Innovation tender called in March 2019, aims to create a dynamic, integrated ecosystem based on new big data collection, management and analysis techniques, in order to provide continuity in treatments for patients with severe pain. The new hub facilitates further digitisation and new integrated, innovative, sustainable care models in which patients in pain can be assured of constant cooperation between and support from healthcare personnel.

MAIN TRENDS

Integrated data collection from self-reported information (from sources such as electronic diaries and planners, special apps and video recordings) is combined with augmented reality techniques and/or specialised treatment devices (e.g. Transcranial Direct-Current Stimulation (TDCS) devices) in order to:

- assess effectiveness of therapies and treatments using reliable, controlled measurements;
- pinpoint areas where further research is needed;
- propose new guidelines or recommendations for personalised pain relief;
- improve surveillance of treatment use.

The total budget for this project is €5,340,117.51, of which €2,701,025.79 is being covered by regional government funds. Led by Istituto Europeo di Oncologia (IEO – the European Oncology Institute), the project's other partner institutions are the University of Trieste, GTS Srl, Nuvyta Srl, Casa di Cura Privata del Politecnico SpA, Zadig Srl, and the Istituto di Management Sanitario Srl.

MAIN TRENDS

ARTIFICIAL INTELLIGENCE

Applying artificial intelligence (AI) to healthcare has become increasingly common, especially in the form of automating certain diagnostic activities that assist doctors in reaching decisions. Nevertheless, there is plenty of room for further improvement, development and extension of AI in healthcare services.

AI can support early diagnoses, by identifying early symptoms or determining in advance the likelihood that patients will contract a given illness. The segment that is benefiting most from this technological progress is diagnostic imaging, where automatic image-reading by advanced software facilitates the radiologist's task. This process is, however, widening the gap between hospitals that can afford to adopt AI techniques to interpret images and those that must make do with traditional methods.

Until recently, AI had been used only for predictive analysis or research, whereas the technology is now being applied to mini-invasive surgical operations that can be performed by robots. AI is now also being used to regulate movements of the human hand in order to prevent any sudden shaking or vibrations. With these advantages, surgical robot production has been a very fast-growing business in Italy for several years.

Other fields of application for AI include improvements to healthcare assistance tasks, the promotion of preventive medicine, and the personalisation of new drugs.

Access to and analysis of vast amounts of data (Big Data) is an essential factor in the effectiveness of AI when applied to healthcare settings, so AI and Big Data solutions are very closely connected with each other.

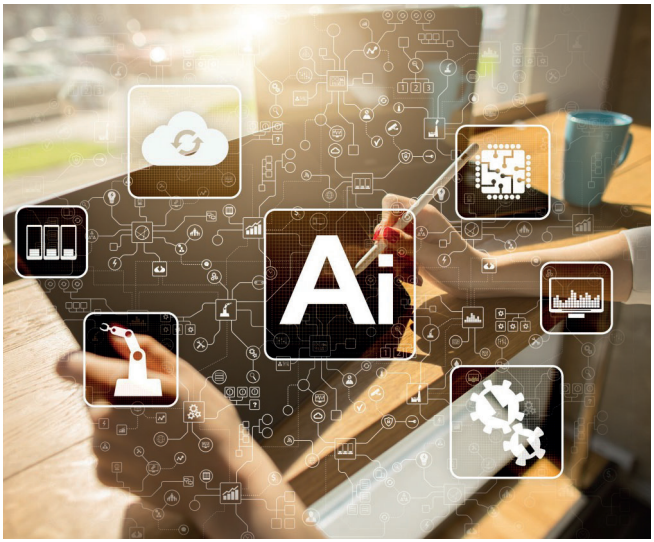
MAIN TRENDS

The following are examples of promising pilot projects in applied AI for life science in Italy:

- Valduce Hospital, Como, automated doctor: a tele-visit system using an inTouch robot, where specialists can communicate in real time with patients who have suffered strokes or trauma, and begin life-saving treatment remotely, well before the patient arrives in hospital, as well as make progress assessments for subsequent rehabilitation;

- the ESH app: enables blood pressure and weight of patients with hypertension to be monitored, by recording data and sending it directly to the patient's doctor for analysis and monitoring;

- Mede Hospital (near Pavia) 2020 pilot project: using a medical device developed by a company based in Tel Aviv, doctors and nurses will be able to check up on patients' conditions without directly seeing or touching them. From a control room, physicians can monitor patient health via sensors placed under the bed frame that detect changes in vital signs. This service can be extended to home care as well, via a closed wifi connection, so that doctors can monitor patients and intervene where necessary.



MAIN TRENDS

GENOMICS

Genomics is the discipline of studying genetic profiles on a broad scale – it is distinct from genetics, which focuses on individual genes one at a time. The process of 'transition' from genetics to genomics is a major development in the life science sector.

DNA sequencing has become an essential tool in biological research. In order to performing DNA sequencing, scientists have in recent years shifted from the Sanger method, where single genes are isolated and analysed, to 'Next Generation Sequencing' where millions of DNA fragments are sequenced at the same time. This new generation sequencing method constitutes a valuable tool for further in-depth analysis in biology and medicine. It is in fact helping scientists craft new models for developing diagnostic tests. New treatment methods facilitated by these new techniques are referred to as 'personalised medicine' or 'precision medicine'. Currently, the most important field of application for personalised medicine is oncology.

Notably, the first '**Genomics Monitor**' in Italy was established in 2020 with the aim of tracking developments in new DNA sequencing technology.

MAIN TRENDS

ARGO Project 2019-2020: the applied research centre Arc -net of the University of Verona is heading up an international consortium for cancer genomics called Accelerating Research in Genomic Oncology (ARGO). This project aims to build an infrastructure network for multi-centre clinical trials in order to bring new drugs onto the market in the near future. Arc-net is working to form a network of high-quality Italian oncology centres. With its hub in Verona, the goal of this network is to make Italy a leading contributor to defining a new era of precision medicine in oncology.

"From Genoimcs to Rare Cancer Therapy" Project 2020: the general purpose of this project is to develop an innovative approach to treating rare cancers, based on the most appropriate cellular models and biological samples, to then develop specific therapies using new-generation methods. Highly innovative sequencing technology will be applied to analyse genomes, even in single cells. This project is led by the Telethon foundation and its partners include the G. Pascale National Tumour Institute, Nouscom Srl, pharma company Dompé Farmaceutici SpA, and Takis Srl. The total budget is €11.8 million, of which €8.146 million is covered by government funding.

MAIN TRENDS

ONLINE ASSISTANCE AND TELE-MEDICINE

Online assistance and telemedicine are further applications of digital technology in the healthcare system that are rapidly progressing, both in Italy and internationally.

Telemedicine can be defined as any technology that facilitates remote patient monitoring by doctors. Particularly on the back of the serious public health emergency caused by Covid-19 that took the country by storm in the early months of 2020 and has necessitated social distancing measures and restrictions on freedom of movement within the country, it has become clearer than ever that the healthcare system cannot be adequately efficient without embracing telemedicine solutions.
Given that chronic illnesses have become more and more common and a priority concern, the use of remote monitoring technology for patients would seem to be a fundamental step forward. Telemedicine solutions enable patients to retain their autonomy and self-sufficiency in the comfort of their own home. It effectively means that a hospital-community-home network is constructed, in which general practitioners, paediatricians, nurses, surgeons and other medical professionals in the various specialisms interact.
More specifically, telemedicine services can be subdivided into:

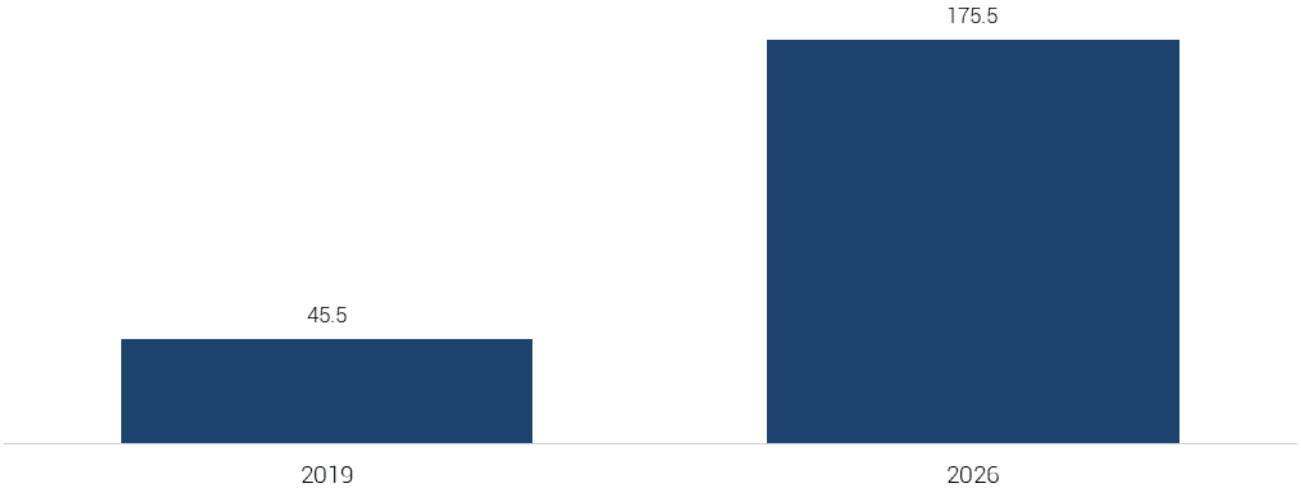
- specialist medical services: remote specialist medical visits, consultations (including those between doctors) and remote cooperation between healthcare institutions;
- telehealth: general primary healthcare provision for patients, especially those with chronic illnesses, provided at a distance by doctors to reach a diagnosis;
- teleassistance: social care services, most notably for the elderly.

The Italian Ministry for Economic Development has allocated funds earmarked under the "Cura Italia" law decree. Specifically, €600 million will fund strategic and innovative programmes around the country that are dedicated to developing the "green economy", biomedicine and telemedicine, with **€200 million allocated specifically to biomedicine and telemedicine projects**. The government has given priority to investments used to manufacture any medical equipment and biomedical material needed to combat the Covid-19 outbreak.

MAIN TRENDS

The global telemedicine market value amounted to €45.5 billion in 2019 and is expected to grow sharply to reach €175.5 billion by 2026.

GLOBAL TELEMEDICINE MARKET, 2019 AND FORECAST FOR 2026
€ bn

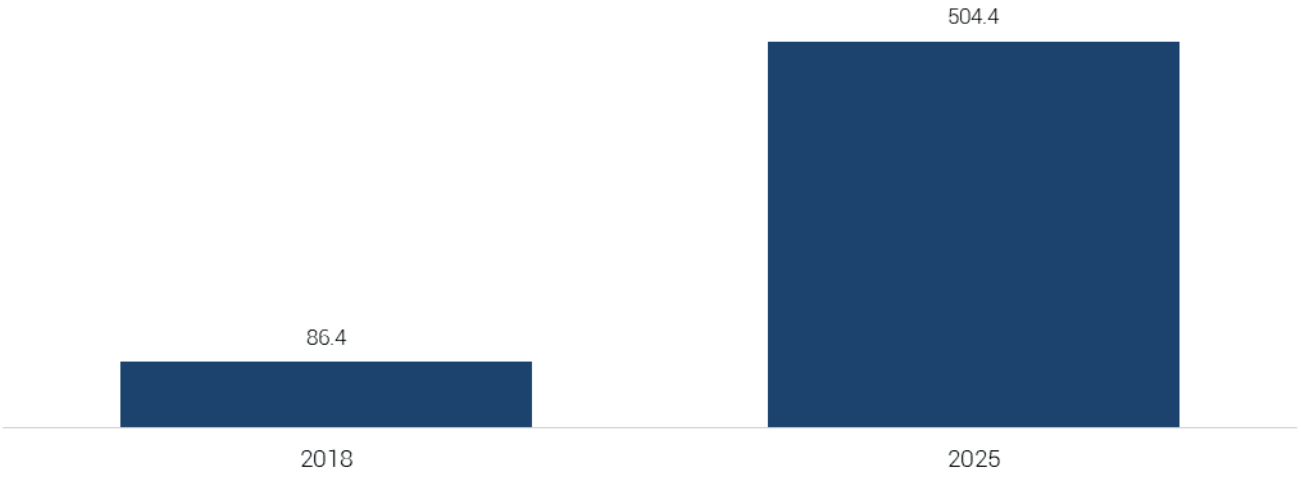


Source: Cerved Group illustration of Statista data

MAIN TRENDS

The global digital health market value amounted to €86.4 billion in 2018 and is forecast to skyrocket to €504.4 billion in 2025.

GLOBAL DIGITAL HEALTH MARKET, 2018 AND FORECAST FOR 2025
€ bn

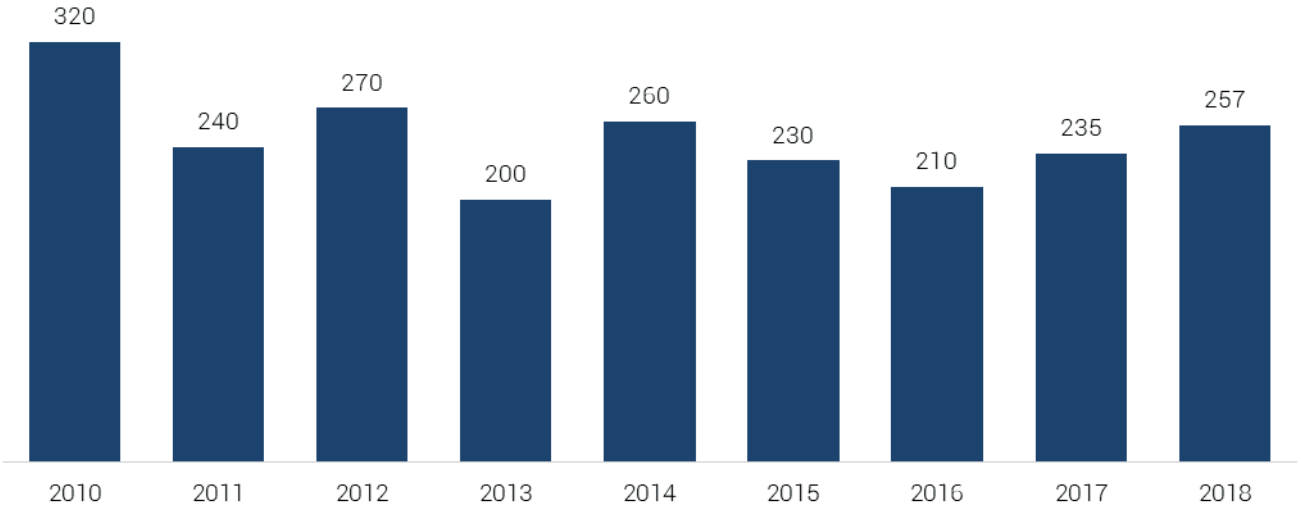


Source: Cerved Group illustration of Statista data

MAIN TRENDS

In Italy, the total amount invested into developing healthcare applications of digital technologies was €257 million in 2018 (the latest year for which data is available – from source Statista), compared to €235 million in 2017.

DIGITAL HEALTH: INVESTMENTS IN DIGITAL TECHNOLOGIES IN ITALY, 2010-2018
€ bn



Source: Cerved Group illustration of Statista data

MAIN TRENDS

VENTURES INTO LIFE SCIENCE BY TECH GIANTS

The influx of digital technology into the life science sector has also brought new players onto the scene, most notably some of the high-tech industry giants. These new entrants are sparking substantial changes in the sector's competitive framework.

APPLE

Apple Over the past few years, Apple has strengthened its business in life sciences by applying its advanced technological know-how to the medical sector. The California-based corporation has developed products such as articles of clothing made with 'smart' high-tech fabrics that can monitor the health of the wearer, by measuring variables such as temperature, blood pressure and heart rate. The Apple Watch makes use of such technology.

Another medical application Apple is pursuing involves taking advantage of the huge pool of iPhone users. In 2015, the company launched ResearchKit, a platform designed for clinical trials (mPwer enabled, in this way, the largest ever study on Parkinson's disease to be conducted). This platform is accompanied by CareKit, an app that lets users monitor any health problems or illnesses and share useful information with their doctors.

GOOGLE

Alphabet, parent company of Google, currently has three subsidiaries active in the life science sector:

- Calico, founded in 2013, performs research and development in biotechnology, with studies on the ageing process and age-correlated diseases and illnesses;
- Verily Life Science, set up in 2015 under the name Google Life Science, performs life science research, especially with the aim of developing solutions to compile and collate healthcare data and analyses;
- DeepMind, established in 2010 and acquired by Google in 2014, works on artificial intelligence applications for the medical sector, specifically AI solutions to prevent and fight diseases.

The amount of resources Google is allocating to start-ups like these clearly shows that Google sees life science as an important sector. Its investment fund **Google Venture has 300 companies in its portfolio, with a combined equity value of €4.5 billion**.

MAIN TRENDS

AMAZON

The American e-commerce leader has intensified its initiatives in the life science sector over the past few years.

As far back as 1999, Amazon had already made its first attempt to penetrate the medical sector, by taking over the pharmaceutical e-commerce business Drugstore.com.

In 2018, the company acquired another online drug retailer, PillPack. Then in 2019, Amazon announced a new joint venture with JPMorgan Chase and Berkshire Hathaway to establish a non-profit healthcare company called Haven.

Amazon also offers I-Cloud services (Amazon Web Service) to:

- improve the use of information about healthcare providers and buyers;
- facilitate the development of new drugs and clinical trials among pharmaceutical and biotech companies;
- conduct experiments in genomics, with automated analytical processes.

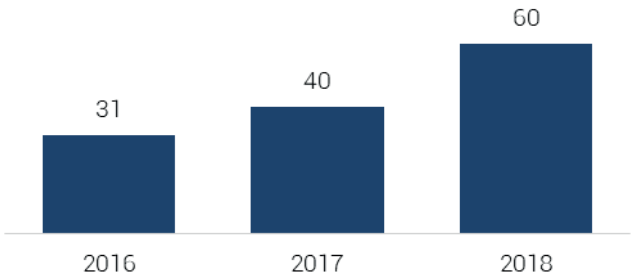
INTERNATIONAL PERSPECTIVE

INVESTMENTS

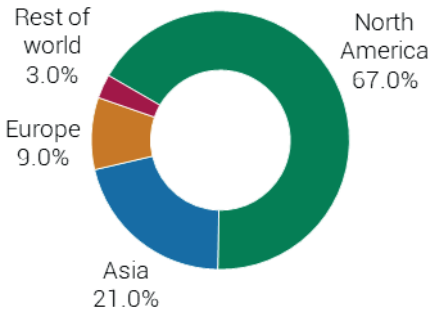
GLOBAL VENTURE CAPITAL INVESTMENTS IN LIFE SCIENCE

According to CB Insights, global investments in venture capital in the life science industry reached €60 billion in 2018, which is 50% more than in 2017 and 93% more than in 2016. Digital businesses, amidst an intense digitalisation process in the healthcare sector, are driving this growth in life science investments. However, only 9% of the 2018 venture capital investments in life science were made in Europe; the leading continent in this regard is North America.

GLOBAL VENTURE CAPITAL INVESTMENTS IN THE LIFE SCIENCE SECTOR, 2016-2018
€ bn



GEOGRAPHICAL BREAKDOWN OF GLOBAL VENTURE CAPITAL INVESTMENTS IN LIFE SCIENCE, 2018
2018: 100% = €60 bn



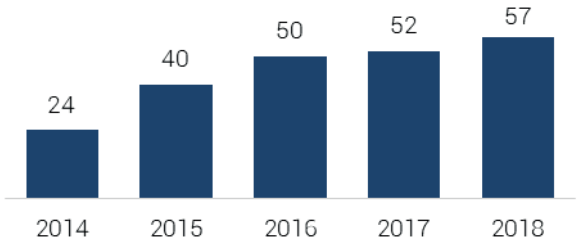
Source: Cerved-Databank illustration of data from CB Insights, 2019 and Technology Forum 2019, Life Science, Ambrosetti

INVESTMENTS

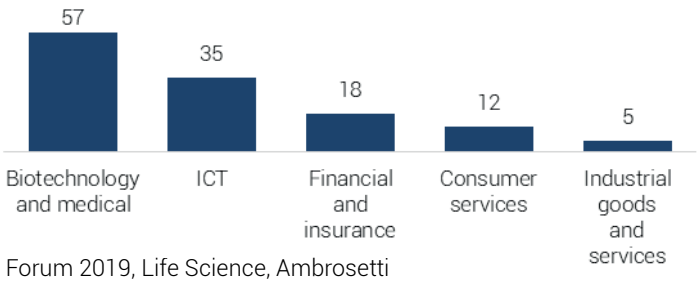
ITALIAN VENTURE CAPITAL AND PRIVATE EQUITY INVESTMENTS IN LIFE SCIENCE, 2018

Life sciences (including the biotech and medical sectors) received the highest number of investments in venture capital and private equity in 2018. The amount invested was €892 million, which is 58% of the total value invested in high-tech business ventures. Therefore, the life science sector can be regarded as one of the most attractive high-tech sectors for venture capital and private equity investors.

LIFE SCIENCE: NUMBER OF VENTURE CAPITAL AND PRIVATE EQUITY TRANSACTIONS IN THE BIOTECH AND PHARMA SECTORS IN ITALY, 2014-2018



LIFE SCIENCE: NUMBER OF VENTURE CAPITAL AND PRIVATE EQUITY TRANSACTIONS IN ITALY BY BUSINESS SECTOR, 2018
(N)



Source: Cerved-Databank illustration of data from Technology Forum 2019, Life Science, Ambrosetti

INVESTMENTS IN ITALY

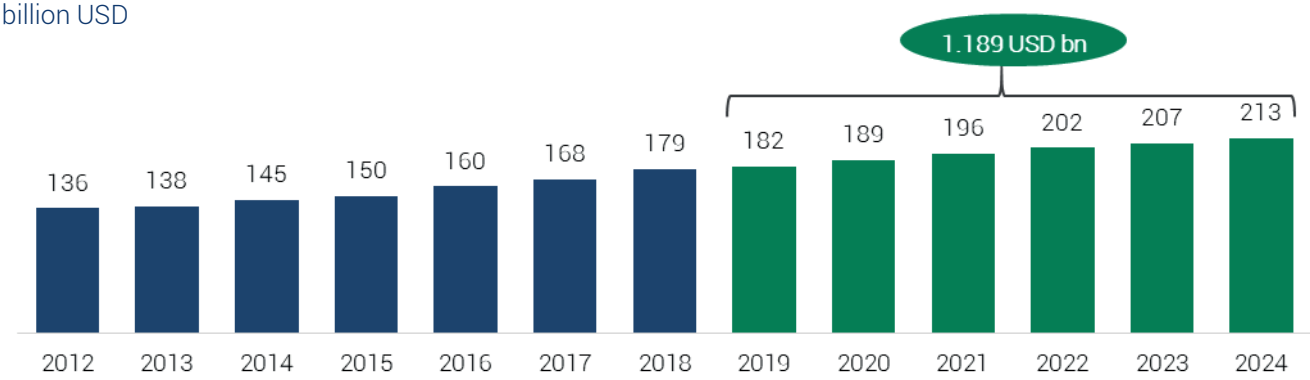
INVESTMENTS IN ITALY: R&D EXPENDITURE

In Italy, the amount **invested in research and development** in the life science macro-sector can be broken down as follows:

- €1.65 billion in 2018 in the pharmaceutical sub-sector (vs. €1.53 billion in 2017);
- €2.26 billion in 2018 in biotechnology (vs. €2.06 billion in 2017);
- €2.20 billion in 2017 in medical devices (latest data available).

At the **global** level, total R&D expenditures in the sector reached **€179 billion** in 2018 including pharmaceuticals and biotechnology. This figure is forecast to increase consistently, with **aggregate expenditures for the five-year period from 2019 to 2024 expected to surpass one trillion US dollars**.

GLOBAL R&D INVESTMENTS BY THE BIOTECH AND PHARMA SECTORS, 2012-2024
billion USD



Source: Cerved-Databank illustration of Evaluate Pharma Report 2019 numbers

INVESTMENTS IN ITALY

FOREIGN DIRECT INVESTMENT

According to the Research on Investments rankings, Italy was among the top 30 "best countries for business" in 2018-2019. Looking at the OECD's 2018 figures on foreign direct investment (FDI), inward FDI stocks for the pharmaceutical sector (economic activity category "Manufacture of basic pharmaceutical products and pharmaceutical preparations") amounted to €6.914 billion, accounting for 1.9% of the country's total inward FDI stocks. In terms of new FDI inflows in the pharmaceutical industry in 2018, these made up 7.1% of all FDI inflows in manufacturing sectors.

ITALY'S INWARD FDI STOCKS[(a)], 2018
€ mn, %

Sector	2018	% of total
Manufacturing	97,059	26.1
of which:		
Manufacture of basic pharmaceutical products and pharmaceutical preparations	6,914	1.9
Other sectors	275,368	73.9
Total	**372,427**	**100.0**

a) FDI positions are total stocks directly held at the end of the period
Source: Cerved Group illustration of OECD data

INVESTMENTS IN ITALY

FOREIGN DIRECT INVESTMENT

With regard to **FDI income** stemming from the "Manufacture of basic pharmaceutical products and pharmaceutical preparations" sector, this figure reached €745 million in 2018.

ITALY'S INWARD FDI INCOME, 2018
€ mn, %

Sector	2018	% of total
Manufacturing	5.998	34,8
of which:		
Manufacture of basic pharmaceutical products and pharmaceutical preparations	745	4,3
Other sectors	11.215	65,2
Total	**17.213**	**100,0**

Source: Cerved Group illustration of OECD data

INVESTMENTS IN ITALY

FOCUS ON THE PHARMACEUTICAL SECTOR: FOREIGN-OWNED COMPANIES

In the Italian pharmaceutical sector, the majority (59%) of the businesses active are foreign-owned, with the other 41% Italian-owned. These foreign-owned companies tend to be highly export-intensive, with 90% of their total revenue coming from exports (compared to 71% among Italian-owned pharma companies).

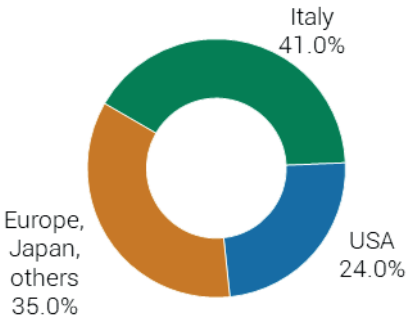
Other key characteristics of the Italian pharmaceutical industry are:

- It is 1st among the major European countries in terms of the number of corporations resident in Germany and in USA.
- It is 2nd among the major European countries in terms of the number of corporations resident in France, Switzerland and Japan.
- It is a **global hub of vaccine production**, with many UK-owned businesses.

All foreign-owned pharmaceutical companies operating in Italy play a significant role in terms of employment numbers, sales abroad and investments.

COMPOSITION OF SHARE CAPITAL OF PHARMACEUTICAL COMPANIES IN ITALY, 2018

2018:100% = 291



Source: Cerved Group illustration of Farmindustria data

INVESTMENTS IN ITALY

FOCUS ON THE BIOTECH SECTOR: FOREIGN-OWNED COMPANIES

According to Assobiotech, only 11% of the biotechnology companies active in Italy are foreign-owned, with most of them focusing their business on human health. Despite this, the sales generated by foreign-owned biotech companies amount to two-thirds (66.7%) of the national total, with the other third generated by Italian-owned companies being more skewed towards the environmental and industrial applications segment.

BIOTECHNOLOGY: NUMBER OF ITALIAN-OWNED AND FOREIGN-OWNED BUSINESSES IN ITALY, 2019

2019: 100% = 696

BIOTECHNOLOGY: SECTOR REVENUE BREAK-DOWN BY OWNERSHIP NATIONALITY, 2018

2018: 100% = €12.1 bn

Source: Cerved Group illustration of Federchimica-Assobiotech data

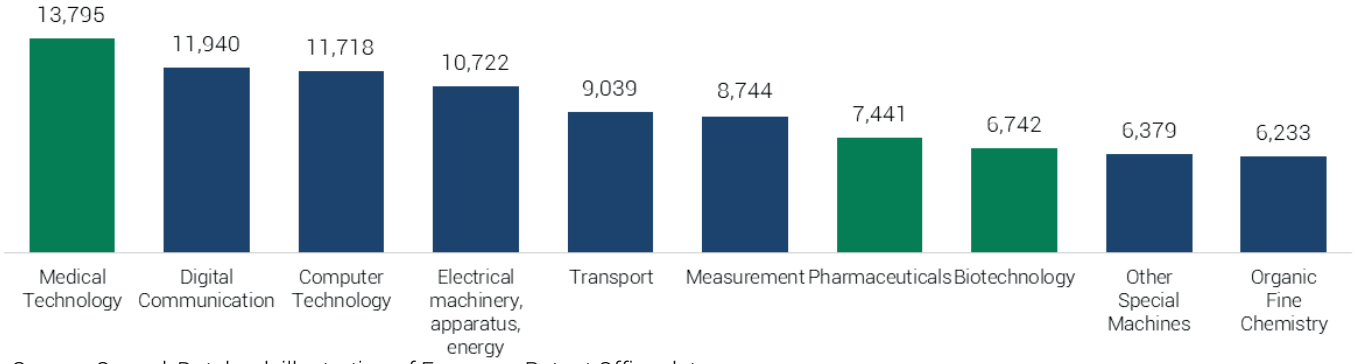
INVESTMENTS IN ITALY

PATENT SCENARIO – IN ITALY AND GLOBALLY

Italy is among the top ten countries for the most life science patent applications submitted. Submissions by Italian applicants to the European Patent Office rose for the fourth consecutive year, a clear consequence of rising investments in research and development. **The medical sector is the number one field for European patent applications**, and experienced a 5% increase in the number of applications from 2017 to 2018.

The medical device/technology area is more prolific for patents than other areas of life science, and saw a 5% year-on-year increase in 2018. Meanwhile, pharmaceuticals (7,441 applications, +13.9%) and biotechnology (6,742, +12.1%) were respectively the 7th and 8th leading sectors in terms of patent applications. Combining all three life science sub-sectors, a total of 27,978 patent applications were filed from Italy in 2018.

THE TOP TEN SECTORS FOR PATENT APPLICATIONS, 2018
(Number of applications)

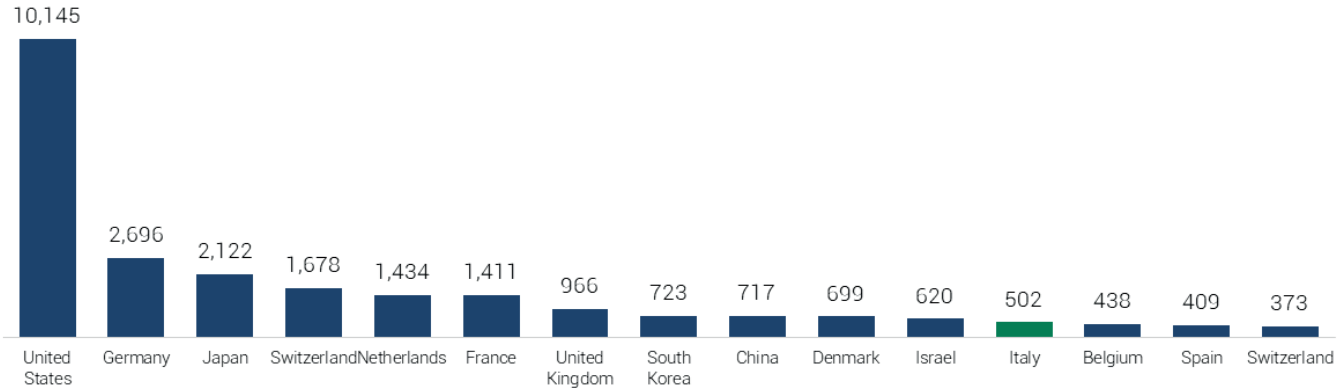


Source: Cerved-Databank illustration of European Patent Office data

INVESTMENTS IN ITALY

Life science can be considered a major patent-yielding field. Medical technology in particular is the area where the most patents have been requested for the last ten years running. By individual country, Germany has been the most prolific in Europe, although the United States is the global leader, far ahead of any other country with 10,145 applications submitted in 2018. Italy comes in 12th place with 502 life science patent applications filed. A notable new entrant is China.

LIFE SCIENCE PATENT APPLICATIONS BY COUNTRY, 2018
(Number of applications)

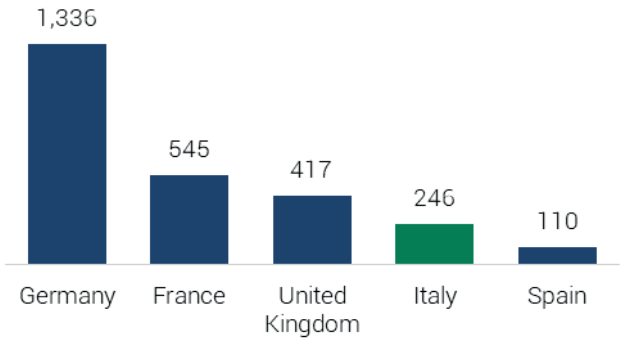


Source: Cerved-Databank illustration of European Patent Office data

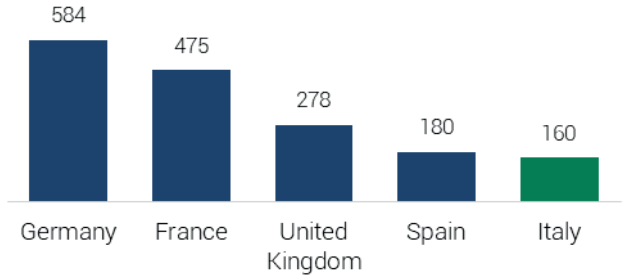
INVESTMENTS IN ITALY

In the medical technology segment, Italy submitted the fourth most patent applications in Europe in 2018 with 246, an 11.2% year-on-year decrease.

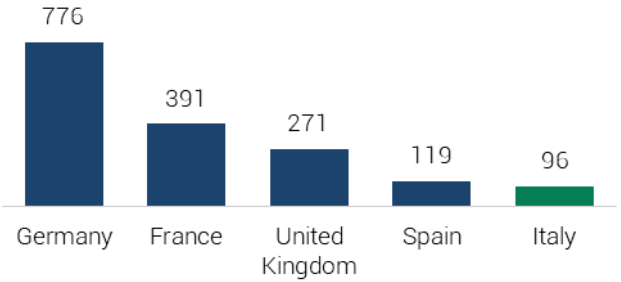
MEDICAL TECHNOLOGY PATENT APPLICATIONS BY COUNTRY, 2018
(Number of applications)



PHARMACEUTICAL PATENT APPLICATIONS BY COUNTRY, 2018
(Number of applications)



BIOTECHNOLOGY PATENT APPLICATIONS BY COUNTRY, 2018
(Number of applications)



Source: Cerved-Databank illustration of European Patent Office data

INVESTMENTS IN ITALY

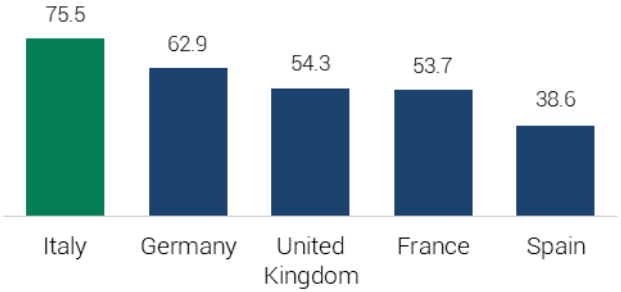
In terms of the number of **patents awarded** around the world in 2018, there were **16,453** in the life science sector, which is 8.8% more than in 2017. The success rate (ratio of patents awarded to applications) was 58.8%.

Italy's success rate in patents overall is second in the world behind France, and its success rate **is number one in the world in life science**. This is evidence that Italy's scientific research in the field is **extremely high in quality**.

Italy's patent success rate is 82.1% in medical technology and 80% in pharmaceuticals, although it falls to 51% in biotechnology.

With regard to publications and clinical trials, Italy occupies the top spot in the world in terms of publications per researcher.

PATENT SUCCESS RATE IN LIFE SCIENCE: TOP FIVE COUNTRIES, 2018
(% of patent applications approved)

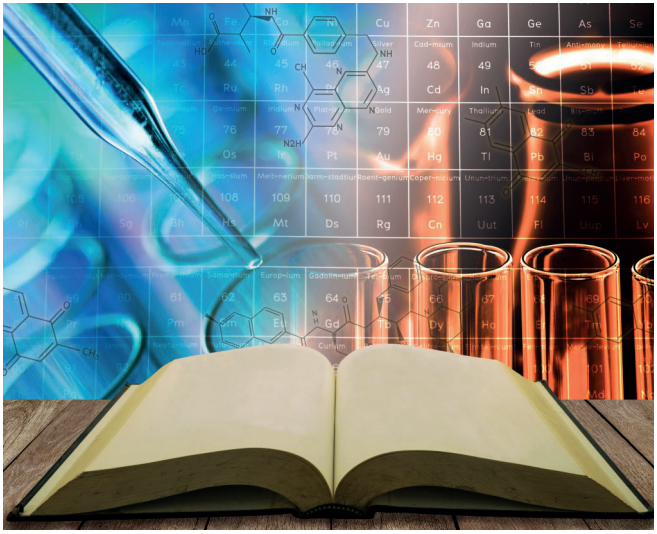


Source: Cerved-Databank illustration of European Patent Office data

INVESTMENTS IN ITALY

By raw number of publications, Italy is:

- 1st in Europe, 2nd in the world in ageing theories
- 1st in Europe, 2nd in the world in endocrinology
- 1st in Europe, 2nd in the world in haematology
- 1st in Europe, 2nd in the world in urology
- 2nd in Europe, 3rd in the world in cardiology and cardiovascular medicine
- 2nd in Europe, 3rd in the world in dermatology
- 2nd in Europe, 3rd in the world in nephrology
- 2nd in Europe e 4th in the world in pharmaceuticals
- 2nd in Europe e 4th in the world in oncology
- 3rd in Europe, 4th in the world in immunology




INDUSTRY ACTRACTIVENESS
BUSINESS
CORPORATE
ENTERPRISE
5659564
5645646
5956564
6564548
1265489
4565456
9894465
3125646
5678987
7643547

INDUSTRY ATTRACTIVENESS RADAR, 2020(a)

a) The smaller the area between the five points, which represent attractiveness factors, the more attractive the sector is for business.

THREAT OF NEW ENTRANTS

The likelihood of new entrants is low due to significant barriers and large investments required to become competitive in the sector. Further challenges for new contenders include complex regulatory issues that govern the pharmaceutical sub-sector, which fosters increasing concentration within this market. The potential for new businesses to penetrate the other two sub-sectors is also relatively low. Investments are highly concentrated among the major companies already active in the sector.

BARGAINING POWER OF SUPPLIERS

In pharmaceuticals, suppliers include pharmaceutical companies themselves, so threats to operating margins from suppliers is low in this area. In the medical devices sector, though, suppliers have medium bargaining power on balance, and it is actually higher against Italian firms than against multinationals that operate in Italy due to the fact that the latter have vertically integrated their production processes. Finally, suppliers that manufacture more sophisticated instruments enjoy higher bargaining power than those that provide raw materials.

INDUSTRY ATTRACTIVENESS RADAR

BARGAINING POWER OF BUYERS

Government policy, medical opinion and pharmacist recommendations significantly influence demand for pharmaceutical products. In the medical devices sub-sector, public sector clients have strong bargaining power through centrally organised tender processes for all the public hospitals belonging to entire regions or cities. It should also be noted that public health service institutions continue to pay their bills very slowly. The average days sales outstanding (DSO) in the sector in Italy is well above the European average. Procurement procedures initiated by private healthcare institutions tend to be much simpler; these clients have medium to high bargaining power.

RIVALRY AMONG EXISTING FIRMS

Competition is intense on the whole, and especially high in the medical devices sector. Manufacturers compete chiefly over prices, with commercial pressures forcing some companies to offer hefty discounts in order to win important supply contracts or to avoid losing clients that bring in high sales figures. In the pharmaceutical sector, pricing is a big factor for generic drugs given that for each prescription drug, a uniform standard sale price to the end customer is established for the entire country. Internationalisation activities are ramping up through mergers and joint ventures.

THREAT OF SUBSTITUTE PRODUCTS

It is low and immaterial in the medical devices segment. In pharmaceuticals, online sales platforms (although these are relatively underdeveloped in Italy) do pose a threat.

OPPORTUNITIES

TECHNOLOGICAL INNOVATIONS AND DIGITAL HEALTH

The continuing digitalisation of the healthcare system is encouraging businesses in the sector to invest more deeply in digital technology. **Advances such as artificial intelligence, big data, automation, 3D printing, cloud computing and blockchain** allow huge sets of data to be generated and analysed promptly and effectively in order to determine appropriate treatments in ways not thought possible until recently. These innovations can also make the processes of clinical research, pharmaceutical manufacturing and personalised treatment plans run more efficiently.

The main ongoing developments in digital health are as follows:

- **Electronic healthcare folders**: in order to eliminate or reduce the need for paper records, the basic information and medical records of each citizen are placed in a single electronic folder that can be accessed by healthcare institutions. With version 2.0 of this programme, big data and artificial intelligence solutions can be used to process the data.
- **Electronic prescriptions**: prescriptions in digital format should simplify the medical care experience for all citizens and help eliminate the errors associated with Italy's traditional handwritten "red slips". Digital prescriptions will also make it easier for the health service to carry out its prescription monitoring activities.
- **Telemedicine**: this is a remote monitoring service especially for patients with chronic illnesses, with the possibility of remote assistance by healthcare professionals.

OPPORTUNITIES

HIGH DEMAND FOR COVID TESTS

The global Covid-19 pandemic, which broke out in Italy in February 2020, has inevitably given companies that operate in the life science sector a major short-term opportunity. For pharmaceutical and biotech businesses, it is in the form of intensive research to find effective treatment and a vaccine against the virus, while companies that manufacture diagnostics products and other medical devices have seen extremely strong demand for molecular test and blood test kits that can detect Sars-Cov-2. Since May 2020 there has been a spike in demand for molecular tests needed to detect the Sars-Cov-2 genome in nasal secretions or in other respiratory system material, as well as for blood tests that detect antibodies.

OPPORTUNITIES

GROWING EXPORTS

Pharmaceutical companies that operate in Italy are characterised by high export intensity: 71% of Italian-owned pharmaceutical companies' sales stem from exports, and that proportion rises to 90% among foreign-owned companies. Pharmaceutical exports have been growing constantly over the past several years. The prospect of continually increasing sales abroad of medicines and other pharmaceutical products certainly constitutes an opportunity for growth in the short to medium term. According to Farmindustria, the EU-28 is currently the geographical area to which the majority of Italian-made pharmaceuticals are exported, accounting for 56.8% of the total. The countries that import the most Italian pharma products are Belgium, Germany and France. Demand from countries outside the EU grew by 7.5% year-on-year in 2018 to reach the remaining 43.2% of total exports, with a sharp 21.7% increase in exports to east Asia.

The medical devices and biotechnology sub-sectors have also witnessed growing demand from abroad, creating an important opportunity for higher sales figures in the short to medium term.

AGEING POPULATION

As the average age of the global population continues to rise, age-related illnesses and conditions are also bringing about considerable opportunities for business growth in the life science sector. In developed/industrialised countries especially, the elderly (over-65) population is rising, accompanied by a constant increase in chronic and/or degenerative diseases. As life expectancy increases and the ratio of economically active to inactive citizens decreases, the socioeconomic burden of health and social care and pension payments to the elderly population will also continue to increase. In this regard, Italy is particularly influenced by this trend, having the highest life expectancy in Europe with over two million people over 85 years old and a record-breaking 14,456 centenarians living in the country as of 2019, 84% of whom are women.

In this context, the pharmaceutical industry is called upon to provide new drugs and new treatment solutions to face the growing portion of the population affected by chronic illnesses.

CRITICAL SUCCESS FACTORS

INVESTMENTS IN R&D

Growing investments in research and development of new technology, particularly in view of the ongoing health service digitalisation process, constitute a critical success factor for life science companies. Innovative technology helps companies improve their performances on the market by upgrading their products and making their production process more cost-efficient.

Especially in the pharmaceutical and biotechnology sectors, the amount of resources devoted to research projects is a significant distinguishing competitive factor – and this also has important effects on improvements in human health.

Scientific and technological developments are enabling pharmaceutical companies to make great progress in both R&D and enabling biotech companies to develop and produce more advanced therapies.

Investments are ramping up especially in digital technology, amidst the ongoing health service digitalisation, with the major investment projects relating to big data, artificial intelligence, telemedicine and electronic medical records.

Specifically, the diagnostic imaging and laboratory analysis segments are the two areas in which R&D investments with digital aims have spread fastest.

CRITICAL SUCCESS FACTORS

In recent years, system-wide expenditure on digital health innovations has been growing: healthcare institutions spent €970 million on digital technology in 2018 alone, according to the Milan Polytechnic University's "Digital Innovation in Healthcare Monitor". This shows how using digital technology to make the national health service more efficient has taken on a strategic role in the sector.

Furthermore, pharmaceutical companies are to an increasing extent also providing services in addition to supplying products.

CRITICAL SUCCESS FACTORS

NEW BUSINESS MODELS, NEW SKILLS

New product technologies and innovative production processes require companies to possess new skills, particularly in the digital domain (e.g. AI and big data), and even to develop new business models. In such a highly dynamic market context, it is no longer sufficient to develop these skills internally (though this is still important). Instead, companies need to change their business models to accommodate interdisciplinary and inter-sector cooperation and partnerships, especially on an international scale. Partnerships have thus become a significant distinguishing factor for production performance improvements.

In addition, Italy's position as the leading pharmaceutical manufacturer in Europe can be attributed to its robust, consolidated manufacturing structure in the sector featuring specialised know-how and high human resource productivity levels.

CRITICAL SUCCESS FACTORS

ORGANISATIONAL CAPABILITIES

Given Italy's leadership in pharmaceutical production in Europe, it is important for companies active in the sector to optimise their production processes by containing costs and keeping flexible organisational structures. In the interest of sustainability, it has also become important for pharmaceutical companies to adopt 'green' practices and adapt their production processes so as to reduce their impact on the environment. The production of pharmaceutical products does in fact have a significant impact on the environment; however, Farmindustria points out how Italian pharma companies have distinguished themselves by paying close attention to environmental issues, making commitments towards sustainability and social and competitive responsibility. Many companies are investing in 'clean' technologies, in the form of production equipment that eliminates or reduces harmful environmental effects. To sum up, the Italian pharmaceutical sector enjoys a highly competitive position thanks to efficient organisational structure combined with an attentiveness for environmental sustainability.

INTERNATIONALISATION

Given the sector's high export intensity, extensive international business activities – whether through partnerships, joint ventures or 'strategic alliances' with foreign companies and institutions – are a key success factor. Internationalisation is indeed a significant driver for growth in the sector. It is also very common among companies in the sector to penetrate foreign markets by establishing commercial subsidiaries in countries where there is high demand for distribution of their products. Finally, mergers and acquisitions are regularly pursued as a way of gaining market shares on an international scale.

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