## THE PHARMACEUTICAL INDUSTRY

a strategic partner for Italy





A WIDESPREAD INDUSTRIAL ASSET
OF NATIONAL AND INTERNATIONAL
COMPANIES FOR THE HEALTH
OF PEOPLE, SOCIETY,
ECONOMY, ENVIRONMENT

In cooperation with





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## INTRODUCTION

"Build back better" was the slogan adopted by the recent G7 meeting to herald its commitment to change. The pandemic has taught us that we need to change many things if we are to make them better than before.

We have learned that health is wealth, freedom, cohesion, community, work, and equality. Without health and investments in the Life Sciences there will be neither a future, nor harmonious social development.

The results of pharmaceutical companies' R&D have been incredible. The discovery in record time of therapies and vaccines and the global production of 11 billion doses within 2021 may allow the whole world to *emerge from the tunnel of the pandemic.* 

And yet while all this happened, the R&D on other pathologies never stopped. In Europe, 55 new medicinal products were approved in 2020, compared to 30 in 2019, and there are *many promising projects in corporate pipelines*.

Pharmaceutical companies have demonstrated the extent of their *innovative* and networking capabilities in combining science and technology, human skills and artificial intelligence, as well as public and private excellencies.

The possibilities of a development that can benefit us all today are enormous. However, without a new or-

ganisation they will remain a dead letter: the speed with which scientific progress becomes available to patients is no longer "only" a scientific question. More and more it is a matter of planning, rules, skills, and decision-making processes. But such factors are also needed to attract investment, and this, today, is more than ever indispensable in the framework of the fierce international competition that is already reshaping the sector's future.

Interpreting the complex multidisciplinary and global processes of the Life Sciences calls for a structured mediation able to bring the protagonists of public and private systems together within a network where all necessary skills can be accessed.

The word **partnership** is not a slogan. It is a **factor in competitive strategy,** indispensable for finding innovative and shared solutions to the country's real needs.

For the pharmaceutical industry partnership means promoting research, creating value while respecting economic, social and environmental sustainability, improving patients' access to treatment, increasing employment and skills, increasing investments in ecological transition, and correctly exploiting the potential of digital transformation.



Thanks to a balanced corporate mix unique in Europe, Italy can play an even more important role on the world stage. A combination of Italian firms, of various sizes - and often with an international reach - and multinationals with global centres of excellence for group activities. The outcome is a system of innovative structured, solid and diversified companies that generates employment, investments, R&D, Open Innovation.

However, if we are to meet the country's shared health and growth goals public health policies must be coordinated with industrial policy.

Coordination entails adequate funding and new spending management models that measure, as with all investments, not only costs but also the clinical, social and economic value generated over time by a given treatment pathway. However, measurement goes well beyond the simple "sum" of the services provided as it is necessary to evaluate the interconnected process integrating research, medicinal products, precision diagnostics, digital innovation and as far as possible, domestic assistance services.

A development of this kind requires the ability to use
the enormous value of data generated by the system health correctly, as it can actually save lives by virtue of the
greater efficiency afforded in terms of care and research.

The One Health paradigm recognizes that human health is linked to the planet's own well-being. The same holistic and circular vision must, however, include an inter-generational pact to ensure that Italy can be guaranteed a continuous stream of innovation, information and investments for the benefit of today's and tomorrow's citizens.

Pharmaceuticals constitute a testbed to measure Italy's willingness to look towards the future.

The industry is ready and willing to proceed, and its skills are honed to strengthen its role as a strategic partner for the country, so that we can together build a resource for health, the economy, society at large and the environment. A resource for life.

Massimo Scaccabarozzi
President of Farmindustria

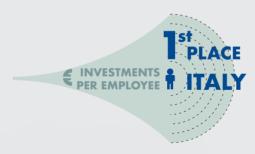
### RESEARCH



#### **INVESTMENT 2020**

€1.6 bn the **resources invested in R&D in Italy** by pharmaceutical companies in 2020.

A value equal to 17% of the sector's value added (against average of 1.4% in the economy at large).



#### **OPEN INNOVATION**

1st place for Italy for Open Innovation investments per employee and for the percentage of companies with **cooperation agreements with universities and public research centres** [80%].



#### **CLINICAL STUDIES**

€ 700 m are invested each year by our companies in clinical studies, **generating new knowledge**, skills and savings for the public and private health system, and making new treatments available.



1st place for Italy in the EU (4th in the world) for scientific publications on Covid-19 of which more than 75% were "open access" publications.



The pharmaceutical industry is a strategic partner for the country. This has been amply demonstrated during the pandemic when the industry lent its valuable help in managing the crisis throughout the national territory and developed, in less than a year, Covid-19 treatments and vaccines. And it is also demonstrated daily by investments in research and by ensuring continuity in the supply of indispensable medicines, vaccines and therapies to prevent and cure diseases that are often rare. And it did this in a year as difficult as 2020; over 90% of the pharmaceutical companies confirmed their investments in R&D, and of these almost 40% actually increased them.

Thanks to this partnership, the sector and the country have, over the years grown together, disseminating new knowledge, skills and good practices, and promoting a **shared culture on new scientific and technological frontiers**.

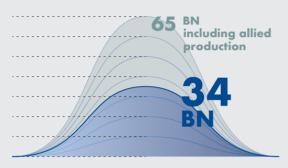
Without such a partnership with public and private research institutions, start-ups, science parks, non-pro-

fit organizations, it would be impossible to excel in all stages of the research process: from studies, to research and experiments, up to care-access for patients. Such cooperation makes the pharmaceutical industry one of most advanced examples of Open Innovation.

The health crisis clearly highlighted the need to redouble cooperation between companies, the institutions and the research system as a means to accelerate current innovative processes and improve citizens' health and life-expectancy, and attract new resources and capabilities for the economic and social development of the country.

Yet in order to attract investment the industry needs instruments and fixed rules to encourage basic research, pursue clinical studies, register and protect patents and carry out technological and digital information transfer, because in so doing it will reinforce the Italian innovation ecosystem, for the benefit of today's and tomorrow's patients.

## **PRODUCTION**



#### **PRODUCTION 2020**

34 billion is the value of the **pharmaceutical industry's production in Italy in 2020**, along with € 1,4 billion in investments in high-tech plant. The value rises to 65 billion when upstream sectors' production is considered.





#### **EXPORT GROWTH 2015-2020**

at +74% export growth in the period 2015-2020 is far superior to that of our EU partners (+48%). The average value of exports also grew (+50%), which is another indicator of innovation and the quality of our production.



#### **VALUE ADDED PER EMPLOYEE**

+12% is the differential between Italy and the average of the major European countries in terms of value added per employee in pharmaceuticals, a fact that highlights the high technological level achieved by production in Italy



#### CONTRACT DEVELOPMENT

1st place in the EU for Contract Development and Manufacturing Organization, an activity with high added value, in active partnerships with other pharmaceutical companies.



Pharmaceutical products are one of the specialties of Made in Italy, as shown by the country's positive trade balance, which in 2020 amounted to more than 4 billion euro. In Italy, the pharmaceutical industry is a widespread productive system that **generates value throughout** the whole national territory, in the shape of 200 large, medium and small Italian and foreign-owned plants.

Thanks to constant investment over time the sector has managed to increase its added value in relation to both turnover and employees and increase the average value of its exports, thereby consolidating an international position characterised by high standards of safety and quality, which in their turn are the product of a long-standing industrial tradition.

The system is premised upon continuity in generating growth, investments, added value, and increasing the production of the more innovative products, such as, for example, biotechnological medicines, vaccines, plasma-derived products, advanced therapies alongside

the production of medicines with consolidated use, and essential for **ensuring the quality of patient care**, in Italy and in Europe.

The system, moreover, relies upon a strong network characterised by many qualities that include not only contract development and manufacturing, in which Italy is a European leader, capable of endowing flexibility, innovation and efficiency to the whole system, but also production chains specialised in the production of manufacturing machinery and an educational system that quarantees the continuous updating of skills.

This industrial fabric can and should be strengthened in close partnership with the institutions by the use of new and better tools for a changing competitive context that can create value for companies of all sizes, wherever situated in the national territory. Only in this way can the health system continue to ensure economic and social development throughout the country and best international competition.

## **ACCESS TO CARE**

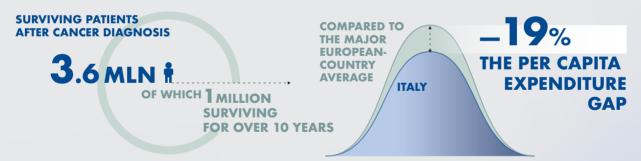


#### **MEDICINAL PRODUCT CONSUMPTION**

26 million people take medicinal products in Italy. This number, which takes account of family members and caregivers, **practically involves the entire population in a daily basis.** 

#### **NEW MEDICINAL PRODUCTS IN THE EU**

55 **new molecules were approved in Europe** in 2020 (+80% compared to 2019).



#### **INNOVATION VALUE**

3.6 million people living in our country after being diagnosed for cancer, approximately 1 million more over a 10-year period, thanks to innovative and personalised treatments plus ever-more home assistance.

#### **PUBLIC PHARMACEUTICAL SPENDING**

-19% is the percentage difference as between per capita public pharmaceutical spending in Italy compared to the average of the major European countries over the last five years. This gap is also evidenced in the access to new products.



The pharmaceutical industry stands side-by-side with Italy, in its continuous search for answers to growing health demand. And it does so by guaranteeing increasingly effective therapies that provide cures or an improved management of pathologies, as also through prevention and ensuring ever more home orientated therapies to improve the quality of life of patients and carers.

The industry promotes the correct use of medicines and vaccines. This not only reduces recourse to hospital admission, preventing illnesses or slowing down their course, but also decreases the cost of social assistance services and avoids additional costs for citizens and the state, and at the same time enables patients to co-exist with their disease, and maintain an active lifestyle.

It is therefore fundamentally important that the country invest in a still **underfunded** pharmaceutical sector

with respect to a growing health demand. For example, it would be sufficient to deploy all the resources available so that the savings made in other services could be used to finance pharmaceutical spending, thereby introducing mechanisms for an overall evaluation of the clinical, social and economic effects of the use of medicinal products, by assessing the efficiency of several years of treatment paths.

As we have come to understand during the pandemic, health and well-being represent key factors for our society and economy. For this reason, it is necessary to develop a new model, no longer simply focused on containing costs, but one oriented towards access to all available therapies. Only in this way shall we be able to strengthen the health system and make it increasingly focused on appropriateness, the recognition of value, innovation and prevention.

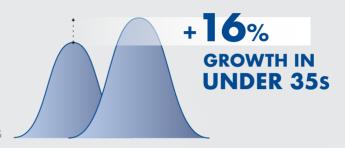
## **EMPLOYMENT**

## EMPLOYEES 67 THOUSAND

OF WHOM 90%

GRADUATES

OR H.S.C GRADUATES



#### PHARMACEUTICAL EMPLOYEES

There are 67 thousand pharmaceutical employees in Italy, a figure that has grown by over 12% in the past 5 years (against the economy's average of +2%). 90% are university and H.S.C graduates..



52% IN RESEARCH AND DEVELOPMENT

**29**% IN OTHER SECTORS

#### **GENERATIONAL TURNOVER**

There has been an over 16% growth in the number of under 35s in the pharmaceutical industry, an **indication of a virtuous generational turnover.** 



#### **WOMEN EMPLOYEES**

43% of pharmaceutical employees are women, a **much** higher figure than in the rest of the economy (29%).

Moreover, a very high percentage of women hold position of responsibility (42% of executives and middle managers are women), while accounting for 52% in R&D.

#### WELFARE AND TRAINING

**1st place in Italy** among the industrial activities as regards, welfare, training and parenting support.



People are the main engine of the economy and it is thanks to excellent human capital that a modern pharmaceutical industry is created.

And the attention of pharmaceutical companies operating in Italy has been particularly concentrated on people and the promotion of their well-being by introducing one of the most advanced and all-embracing corporate welfare schemes for employees: a scheme that strikes an optimum work-life balance, enhances health and well-being to employees and their loved ones, provides assistance to elderly or non-self-sufficient family members and support for parents, as well as delivering educational, social and health assistance services together with collective transport and company canteens.

These activities are also the outcome of the innovative industrial relations that the pharmaceutical companies have wisely cultivated and whose best practices are supplemented by initiatives that accompany employees throughout their entire lives, including the imparting and acquisition of multi-disciplinary skills, teamworking aptitudes, and those digital and soft skills that are increasingly important in both everyday life and gainful employment.

But as regards employment our attention is firmly fixed on the future.

Companies are committed to bringing young people closer to the pharmaceutical industry and the life sciences, by stimulating those talents and passions that represent necessary preconditions for guaranteeing a virtuous generational turnover.

Farmindustria has developed a unique model within the Confindustria System, together with its associate companies, in the form of intense activities **based on alternate** school and work training, which since 2017 has involved 13 schools and 300 students, with 1,000 hours of theoretical lessons and project work, over 700 hours of company internships, and a solid collaboration with the national network of ITS in New Life Technologies so as to impart the profiles and skills required by companies.

Ever-greater attention is being given to this scheme by investing further resources and skills in partnerships with institutions, allied-production companies, trade unions, local associations, the tertiary sector, thereby allowing students to acquire direct experience of the workplace and training on matters of great social and health importance, such as vaccination prevention and antibiotic resistance.

## THE ENVIRONMENT

**IN 10 YEARS** 

-59%
ENERGY
SAVINGS

**IN 10 YEARS** 

-32% EMISSIONS AVOIDED

\_17%
MANUFACTURING AVERAGE

MANUFACTURING AVERAGE

#### **ENERGY CONSUMPTION**

a 59% reduction in energy consumption by the pharma industry in Italy over 10 years, a percentage that is three times higher than the manufacturing average (- 17%).

#### **EMISSIONS**

a 32% reduction in greenhouse **gas emissions in pharma companies in Italy** over 10 years, compared to the manufacturing average of -28%.





#### **ENVIRONMENTAL PROTECTION**

150% is the positive difference in the value of investments in environmental protection calculated per employee in the pharmaceutical industry compared to the national manufacturing average.

#### **WASTE REDUCTION**

88% is the percentage of companies that will reduce the waste they produce in the next 3/5 years, while 55% are committed to reducing/eliminating the use of plastics at every stage of the production process.



The current pandemic crisis clearly illustrates the strong link between health and the environment, as the One Health model so clearly sets out. Over time this link has led the pharmaceutical industry to adopt all the UN 2030 Sustainable Development Goals and create, in 2015, the Eco-Pharmaco--Stewardship (EPS), a European programme for the intelligent and sustainable management of medicines' environmental impact.

By underwriting this goal pharmaceutical companies are committed to improving the entire life cycle of medicines by undertaking major technology investments to curtail their environmental impact, comprising 47% of all eco-investments (against 31% of the Italian industrial average) and by the use of internationally recognized certification.

With the spread of personalized therapies, the resources deployed for treatment pathways – but without impairing their effectiveness - are dwindling, and thanks to a centralized system for disposing of expired or unsold medicines (Assinde) the industry has, for 40 years, continuously improved the management of returned products.

This ongoing commitment has made it possible to reduce energy and water consumption and climate-altering emissions as also to reduce the use of materials and increase the recovery/recycling of packaging materials.

Also as regards environmental issues, the industry can and wants to be at the side of our country committed, as it is, to ecological transition in line with the European Green Deal and the Next Generation EU objectives as incorporated in the NRRP.

## DIGITAL TRANSFORMATION

92% INVESTING COMPANIES IN 2020

222 TELEMEDICINE

MAR APR 2020 2021

#### **INVESTMENTS**

92% of pharmaceutical companies in 2020 **maintained or increased investment** in digital technologies.

#### **TELEMEDICINE**

222 telemedicine initiatives were implemented between March 2020 and April 2021, many on platforms for cooperation developed in association with companies.

61% COMPANIES

PROJECTS IN Cloud, Big data, AI, IoT, Robotics 60%
CLINICAL STUDIES
WITH DIGITAL/REMOTE
COMPONENTS

#### **DIGITAL INNOVATION**

**61% of pharmaceutical companies** in 2020 developed projects involving the cloud, platforms for cooperation, big data, artificial intelligence, the Internet of Things and advanced robotics.

#### **DIGITAL AND CLINICAL STUDIES**

**60% of clinical studies** carried out in Italy between 2019 and 2021 made use of digital technologies or platforms (*Decentralized Clinical Trials*).



Covid-19 marked a watershed in digital health, where "before" comprised years of fragmented experimentation and planning, and "after" was made up of very rapid challenges that called for renewed partnerships between industry and institutions, and major changes in terms of management, integration, and interoperability.

The increase in telemedicine initiatives, occasioned by patients' difficulties in accessing clinics and hospitals during lockdown, has contributed towards the spread of digital health. The use of services, such as televisiting, has grown, become permanent and in some cases such assistance is now reimbursable by the National Health Service, while patient support programmes for remote patient assistance is being provided by specialized teams. The institutions, doctors, patients and citizens have increased familiarity with and trust in such technologies.

As a matter of fact this change is marking more a **cultural rather than a digital transition**, and it is one to which the pharmaceutical companies are committed to

follow through by investments in new skills and new care pathways that will improve the quality of the work of health professionals and significantly enhance the well-being of patients.

The transition constitutes an important challenge that will enable considerably faster and more efficient research processes (Decentralized Clinical Trials, for example), operational continuity, the sharing information over the cloud and the implementation of platforms for cooperation with doctors and patients.

The pandemic has taught us that an additional item is necessary if we are to meet this challenge: **organized and accessible data for safeguarding public health collected in full respect of privacy concerns**, which will enable us to improve treatments, prevent diseases and viral pandemic or bacterial events. Such public and private data would also make it possible to correctly assess the impact of digital technologies and their interactions with medicines (as in the case of Digital Therapeutics).

# COMPANIES IN THE TERRITORY

**2020 DATA** 

EMPLOYEES

67
THOUSAND TO SWHOM 90%

MORE THAN

GRADUATES
OR H.S.C GRADUATES

85%
DETERMINED
BY EXPORT
the last 5 years

**PRODUCTION** 

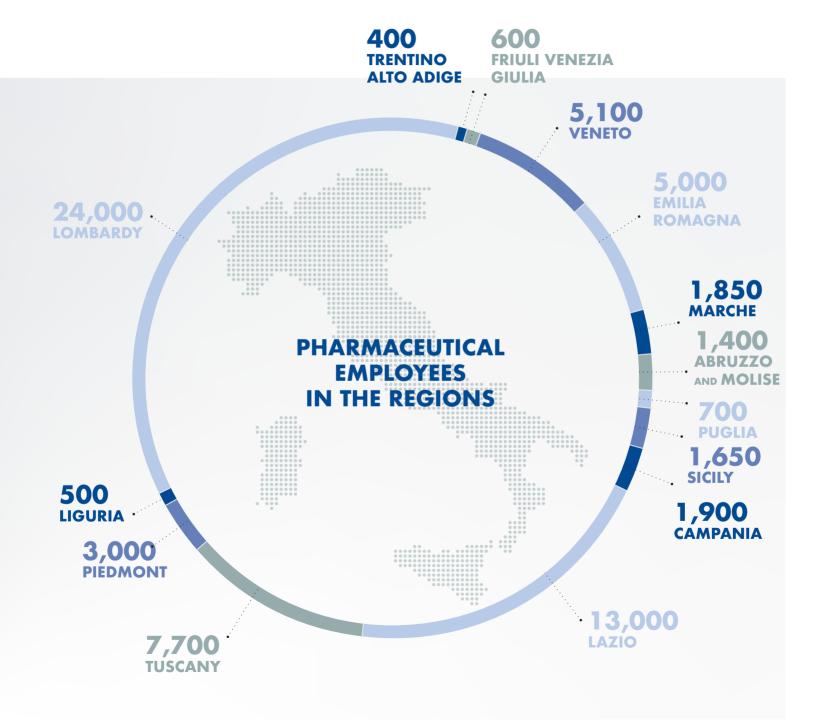
INVESTIMENTI

1.6
R&D
BN
1.4
PRODUCTION
PLANTS



WITH ASSOCIATED PRODUCTION







Founded in May 1978, Farmindustria is an association of pharmaceutical companies. It is a member of Confindustria, the European Federation (EFPIA) and the International Federation (IFPMA). Its members, Italian and foreign-owned companies operating in Italy, number about 200.

The association promotes the value of medicines from a therapeutic, industrial, economic and social standpoint by heightening awareness of pharmaceutical companies and their contribution to the entire economy in terms of research, innovation, and the generation of value.

Moreover, it pursues the creation of a stable regulatory environment and a medicines policy that recognizes the vital role they play in the growth of life sciences in the country.