



THE PHARMACEUTICAL INDUSTRY
A strategic partner for the country.

Public Assembly
Rome, 8 July 2021

ADDRESS BY THE PRESIDENT
Massimo Scaccabarozzi

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Good morning. A very good morning to everybody present here today and to all participating remotely. We are still, alas, operating in a hybrid form, a term we have learned to use throughout these long months, but we would have much preferred to have you all physically present today.

Many participants, all together.

But my first thought, speaking of today's attendance, cannot but go to all those who in this terrible period - for Covid or with Covid - are no longer amongst us.

I wish to greet and thank all of you. But first and foremost, my thanks go out to patients, *persons* under medical care, and their associations.

My greetings and thanks also go out to the representatives of all the institutions and bodies but especially to Parliament, the Government, the Regions, the National Security Force, the bodies dedicated to public health, the associations of doctors and pharmacists, the Judiciary, and the Trade Unions. Moreover, I must greet and thank all of you who have chosen to honour us by participating directly or online.

And of course, an affectionate greeting to my colleagues of our member companies, to the Confindustria network and to all my Farmindustria colleagues, to whom my most sincere thanks are due.

United once again in our usual public meeting after two years' absence for well-known reasons should we begin by saying: what happened?

Yes, because during this period the world underwent extraordinary changes and the terrible ordeal represented by the global contagion has thrown economies and companies throughout the world into a state of turmoil, thereby highlighting the **centrality of health**.

I can quote Pope Francis declaration at the beginning of the pandemic: "*The only thing worse than this crisis would be the drama of squandering its message*". You see, this experience has taught us many things including our fragility and the necessity of being able to anticipate and manage a collective emergency. How? **By redesigning future healthcare**, all together, commencing from the premise that there can be no future without health.

Yet health today, for its part, entails research, digitalization, advanced robotics, ecological transition, quality work, continuous training and investment in the new generations, social cohesion.

The pharmaceutical production chain is all of this and in Italy it is far more widespread and entrenched than you would believe.

We all, companies and representative associations, have raced through the past months at a rate of knots. However, the urgency was not only dictated by the need to chase up problems and solutions but also by the pressing need to **anticipate themes and decision-making processes by loyally cooperating with the institutions**. In this regard our thanks are due, and not merely as a matter of form, to the competent Ministers, the decision-making Councils, AIFA's offices, the Extraordinary Commissioner and his offices, and the Presidents and Councillors of all the Regions. And, moreover, a special thank you to the doctors and all health professionals. We have been in a direct contact, night and day, with all of them, and thanks to this cooperation we have been able to achieve significant results in terms of public health.

In this context, Farmindustria has been a helpful intermediary between the pharmaceutical companies and the authorities, working to facilitate internal harmony and assist the Government reconcile particular and general interests. The association has also activated several strategic Groups for purposes of analysing the many variables of a scenario undergoing major and continuous changes

in order to always be more proactive on issues such as research, production, access, work, sustainability, digital technology and connected care.

Even though we have had to deal with three different governments since the beginning of the legislature, as well as with the Regions and Europe, we can claim to have been recognised and appreciated for the complexity of the system we represent. The pharmaceutical industry has long since ceased to be just research, production and distribution as it now operates through **partnerships** with institutions and professions, including processes and services dedicated to public health and to the personalization of the treatment of individual patients.

And this is a framework that requires the coordination of health and industrial **policies** and **continuous and positive dialogue**.

This dialogue has allowed decision-makers and society at large to learn more about and appreciate the **value that pharmaceutical companies represent for Italy**: the new frontiers of innovation, the efficiency of our organization for continuity of care, our contribution towards the development of clinical and university excellence, and the importance of productive autonomy with respect to the more troubled geopolitical areas.

Today we want, first and foremost, to thank **Premier Mario Draghi** and his government for the authority exhibited in international scenarios as the European Union's approval of the NRRP clearly demonstrates.

And we want to thank him in particular for having asserted that “*Italian **research and the life sciences**’ industry are already **at the forefront** in Europe and the world, and we will do everything to ensure that they remain there*”.

However, such leadership is being brought into question by strong global competitors whose growth, in recent years, has been faster and greater than our own thanks to targeted investment policies and the strategies adopted by their respective governments.

For this reason, it is important:

- to act quickly, after years of underfunding, and **adapt resources to the health needs** of citizens and an ageing population;
- **to eliminate overweening bureaucratic complexities and adapt to the pace** at which the life sciences are developing;
- **to adapt governance and regulations to the radical changes underway** that have transformed medicines from products to processes and to the subsequent global R&D competition;
- **to recognize patent protection**, especially in view of the recent and incredible calls for its suspension or even cancellation, without taking into adequate consideration the market dynamics and benefits that this protection generates and the consequent and evident superiority of Western medicine over authoritarian systems where transparency and the full sharing of information is not practised.

Italy is fortunate to have a **universal National Health Service**, recognized by the Constitution. However, it needs unification, with respect to its regional and infra-regional differences, as well as improvements to primary care services and reorganisation to meet the criteria of patient care and continuity of care.

In particular, with the arrival of **increasingly advanced and personalized therapies**, we need to **rethink the governance** and financing of pharmaceutical spending models.

As a matter of fact, this area of public spending is still premised on a system of spending ceilings introduced in 2007 that although belonging to **a world of the past**, imposes extremely high costs on companies by requiring them to make good overspending on pharmaceutical expenditures for innovative hospital treatments; an area whose annual increases are by now a permanent fixture of the public health system.

Today **health is correctly and widely understood to be a strategic investment** and a matter of national security. Therefore, **pharmacological innovation must be measured by taking its holistic value into account**, starting from the low costs incurred throughout the entire course of treatment. Instead, we still have to deal with an industrial remuneration system stuck in 2009, with medicinal procurement methods based on calls for tenders whose rules fail to take account of quality, technological advancement or overall therapeutic value.

On the other hand, during the pandemic, the **partnership with both individual Regions** and the Health Commission of their Conference, coordinated by Councillor Raffaele Donini, has improved immensely.

The Minister for Regional Affairs and Autonomies, Maria Stella Gelmini, who has played a highly relevant and constructive role, recently highlighted, in one of her declarations, the important role that the Regions will have to play as regards the governance and simplifications decree, by creating "... the conditions to boost reform and investments".

The primary objective must be to **bring innovation ever closer to each patient throughout the entire national territory**. We have already proposed to continue this cooperation by setting up thematic round tables with the Health Commission, in addition to the partnership necessary at the pandemic phase.

In this regard, we would like to recall the joint communication campaign of Farmindustria and AIFA designed to offer the guarantee of a common commitment for the pharmacological needs created by the emergency.

Since the start of the pandemic, both Parliament and Government have enacted legal measures that recognise **pharmaceuticals as an essential activity**, thus allowing companies, even during full lockdown, to operate non-stop and **produce the medicines patients need continuously day and night. Similarly, we have been able to cooperate successfully with AIFA and the Regions to quickly overcome limitations and shortcomings.**

In this context we also owe heartfelt thanks to all production employees who risked their health when the rest of Italy was in lockdown. Despite working in conditions of maximum safety with new production procedures, they never stopped working so that all patients, whether Covid and non-Covid, were able to receive the medicines they needed without interruption.

Our **companies** have been **engaged in the development of Covid vaccines** and in their production during the clinical trial phases without any guarantee of approval and, hence at their own risk.

The cooperation initiated in Italy with the Minister of Health, Roberto Speranza, and the European Commission and more generally with all Western countries will lead to the production of **about 11 billion doses of Covid-19 vaccines for the world by 2021**. An unthinkable high number for a disease that was unknown a year or so ago and which will permit rapid vaccination processes across the planet, including the poorest and most exposed areas.

Thanks to an intuition of Minister Speranza, today **we are part of a European reservation circuit** which, albeit unjustly criticized, made it possible to ensure that

no European nation has been disadvantaged at the expense of other member states. This arrangement has ensured fairness and allowed us, if we look at past experiences, to make vaccines available to other countries in an equitable manner.

We as companies are ready to handle this humanitarian emergency with those decisive forward-looking actions that are absolutely necessary if the disease is to be defeated.

This is a complex operation but one that must be carried out soon, and in the manner suggested by the European and International Federations of pharmaceutical companies, namely by:

- **increasing the sharing out of doses**
- **optimizing production**
- **eliminating trade barriers**
- **enhancing distribution in low- and middle-income countries**
- **developing new vaccines and therapies.**

Pharmaceutical companies are ready to redouble their efforts once again, also as vaccination hubs for all citizens throughout the country - an initiative launched by Confindustria.

The regulatory authorities activated new and unprecedented operating procedures. First, the **rolling review** implemented by the EMA, that closely monitored research activities to determine the safety and efficacy of vaccines. This, furthermore, has been complemented by a wholly innovative ongoing dialogue with companies, which should become a permanent fixture.

Thanks to this partnership **290 vaccine projects have been developed, of which 105 are now at the clinical phase, while 4 have received** European marketing authorizations, and this number could very soon be followed by other authorisations. But, nevertheless, revolutionary, radical, incremental and process-based

research, is advancing in every therapeutic area. In 2020, **55 medicines were authorized in the EU by EMA** compared to 33 in 2019. And with reference to these we cannot but mention the progress made in Covid research which produced monoclonal, antiviral and plasma-derived antibodies.

This traumatic season has prompted regulators to rethink their traditional *modus operandi*. We are closely following the self-reform process that began with EMA, confident that this will serve as a positive model for national authorities or agencies.

The partnership with the Ministry of Economic Development and with the Minister Giancarlo Giorgetti has laid the foundations for identifying **sites to produce Covid vaccines as well as research poles for medicinal products and vaccines in Italy**, in keeping with Europe's aim to become strategically independent in these fields. An unprecedented partnership that has enabled us to demonstrate and further comprehend strategic value of our sector and the need for important reforms.

We acknowledge that the Government has, in the course of only a few months, introduced or strengthened concrete incentive measures for research - such as tax credits - and production, thus opening a new phase of investment support, and which we hope will be consolidated, with **new and more flexible tools in order to afford greater structural strength to the Life Sciences supply chain**, and not only in response to Covid, thereby overcoming the limitations posed by the current regime of European state aid .

However, these actions are in tune with what is happening in other European countries, in France for example, as well as in the USA, where President Biden in the first 100 days of his mandate launched a plan to strengthen strategic supply chains, including pharmaceuticals. And these measures not only regard advanced production systems but also active ingredients and products with consolidated use.

In relation to defence policies, this testifies the key role the sector now plays for national security. Similarly, the sector's importance is also signalled by the growing competition between countries to acquire a significant pharmaceutical presence within their own national boundaries.

Thankfully, the **NRRP can now provide the funding necessary for re-engineering the NHS including investments in the health sector.**

This would be the right time to **argue that all expenses earmarked to the sector should be excluded from the Stability Pact** and more in general from European constraints. They are investments for the future just as R&D expenditure is.

Obviously, in view of that ingrained inability to spend and the slowness in allocating resources that for too many years have bedevilled the State's functions, we must once again highlight **the importance of speed and therefore of simplicity as regards the execution of NRRP plans.**

There are **\$ 1.5 trillion ready to be invested in research around the world from 2020 to 2026.** This value is equivalent to almost 7 NRRPs. I believe that we all share a sense of **responsibility in wanting to attract as much of this spending as possible** to Italy, especially given the quality exhibited by the country in clinical trials is internationally recognized. According to a recent study by the Catholic University's Superior School of Economics and Management of Health Systems, this is an area in which, every year we invest around 700 million in research and for every euro invested 2.8 euro are generated for the national system. However, paradoxically, we are still awaiting the Executive Decrees for the 2018 law governing inward investments, with the danger that our country will be shouldered out of line by other European and first-world countries. For our part, we have been and remain active along with AIFA and the Health Ministry so that the foregoing decrees can be quickly defined.

Similarly, we are also working to implement **digital-technology innovation in clinical trials, with the so-called Decentralized Clinical Trials**, on which we are already conducting in-depth study with the Italian Institute of Health.

Furthermore, with the prospect of a solid and attractive NRRP, we are ready with **4.7 billion in additional investments in production and research for the next three years**, with easily implementable projects that could create **8,000 new jobs** in Italy alone.

Side by side with the endeavours to attract investments, we should not forget the objective of strengthening and reorganizing the Medicines Agency. AIFA is undoubtedly handicapped by being relatively understaffed, compared to other countries, but it is also disadvantaged by the complexity of some of its procedures and by its traditional approach to determining prices. Every delay is ultimately borne by the patients.

Finally, the **pandemic experience has taught us to pay greater attention to public health** also in relation to other sources of danger such as bacterial infections, bioterrorism, and cyber security.

The WHO has for some considerable time been reporting on the **risks associated with the worldwide phenomenon of antibiotic resistance**. Hence the need to quickly initiate research to discover new generation antibiotics. Only a systemic approach involving both states and companies can provide the conditions for addressing the problem before it becomes another worldwide drama. Whether viruses or bacteria, we cannot afford to be caught unprepared. Never again! The price to pay in human lives and in the economy is too high.

Italy is a reservoir of resources and excellence in Life Sciences with little-known or even unknown industrial enterprises, and sometimes even to insiders.

We are already involved in the production phases of various anti-Covid vaccines, thanks also to companies playing a leading role in evaluating vaccine candidates and producing experimental batches. It is our hope that this presence will continue to grow along with the work that the Ministry of Economic Development is carrying out hand-in-hand with the industry. We have excellent projects for monoclonal antibodies originating in Italian companies, multinationals and in partnerships between them. Italy is part of the international antiviral production network and at the forefront of biomedical publications, rapid tests and clinical studies, including oral therapy studies. And **Italian research** has recently developed antibodies for Sars-CoV-2 and **continues to work** for an immunoglobulin to combat Sars-CoV-2.

For many other pathologies too, our **country has become home to outstanding global centres of excellence for both research**, with clinical study activities and advanced open innovation programmes, **and production**, with facilities recognized as some of the most advanced in the world in terms of environmental and technological standards.

These activities address, for example, oncological medicinal products, new generation antibiotics, plasma-derived products, products covered by patents that have made it possible to bring the entire supply chain back to Italy, immunotherapies, orphan medicines, mRNA technologies, insulin and innovative antidiabetic products, injective and sterile products, innovative medicines for heart failure or hepatitis, non-covid vaccines rendered more effective by adjuvants, aseptic medicines, active ingredients and innovative nanomaterials.

In this respect we should note that some Italian companies: have discovered the first cell therapy or medicines awarded FDA breakthrough innovation status; are world leaders in neonatal products; perform the lipid productions necessary for the intake of mRNA medicines; are engaged in innovative therapies against neurodegenerative diseases.

Similarly, small Italian companies are cooperating on digital health projects with Israeli companies to develop cutting-edge technologies, while others are producing monoclonal antibodies for the USA, elaborating new technologies in association with large international groups, making courageous investments in vaccine production, and are recently in receipt of EMA clearance for early detection medicines for Alzheimer.

The world's best artificial intelligence supercomputing platform is Italian, capable of processing 3 million molecules per second to speed up research processes.

And in Italy, excellences in Connected Health have been developed that are unique in Europe as regards the capacity to measure clinical outcomes, along with innovative and integrated real-life data platforms, for monitoring spending and its appropriateness. These examples testify, together with many others, the country's considerable know-how in procedures for accessing the most innovative therapies, as also extremely advanced reimbursement schemes.

The pharmaceutical industry in our country is a vital and multi-faceted world, especially at the local level, where it plays a highly significant role not only from a purely economic point of view but also as a driving force for innovation, research, training, environmental culture, work relations and overcoming gender gaps.

Italy, together with France and Germany, is the among the leaders in pharmaceutical production in the EU, recognized as such by our most important partners. The sector contributes to the country's wealth by generating over € 34 billion thanks to a **system, unique in Europe**, that comprises **Italian companies** of various sizes and often with an international reach, together with **multinational groups**, whose value is expressed through direct investments or production on behalf of third parties, not to mention their commitment to clinical research and experimentation and Open Innovation. Nor should we underestimate that fabric of **small and medium-sized national companies** that enriches many areas of the country.

This extraordinary and original dimension with respect to the rest of Europe is largely the result of the quality of the human capital available, and to which we ourselves have contributed over the years through cooperative programmes with schools and Universities, and through innovative and continuous relations with the Trade Unions.

At 43%, the percentage of female employees in the industry is significantly high, but we must also consider that 42% of executive positions are held by women. And looking towards the future, we have been working for some time on training and virtuous generational change. Thus, there has been a **16% growth in employees under 35** in the sector over the last five years.

Lastly, our companies' alignment with G20 **priorities** should be mentioned, which count health, **ecological transition** and **digitalization** among its global missions.

We have **reduced energy consumption in Italy by 59% over the past 10 years**, compared to a manufacturing average of only 17%. **More than 90%** of the pharmaceutical companies have maintained or increased their **investments in research and digital technologies** to improve access to treatment and therapeutic continuity.

Thanks to the necessary development of **cooperation between the State and the companies** another possible objective to be achieved will be **the collection of big data on health, for subsequent filing and analysis**, and for which the interoperability criteria of information systems will be essential.

Our reputation has grown with the experience of contagion despite the limitations implicit in a search for vaccines, which was also a race against time and in the face of a fear-driven ideological resistance. According to a recent survey carried out by Euromedia Research, 85.4% of Italians believe that research and discoveries in the pharmaceutical industry have had a positive impact on health and the quality of life.

And **72 % of the population recognized that the sector played an active role in the management of the pandemic emergency.**

Dear colleagues, kind guests!

The success of a newly found normality is the fundamental basis for an economic recovery to which the entire Confindustria system led by President Carlo Bonomi is offering its full contribution. And we are proudly part of a system that, by its very nature, is **dedicated to building bridges and solutions.**

I hope that this address has demonstrated our steadfast resolve and capability to **be a strategic partner for the country** and to constitute an asset for the health and well-being of the people, the economy, society and the environment.

And, as always on these occasions, permit me to add one final thought.

This has been, and in some ways still remains, a dramatically difficult period.

We have witnessed and heard so much. Alongside the tragedies of families who have lost their loved ones, there has been a stampede to highlight and communicate problems to the exclusion of stories that could instil hope, trust, optimism; stories, in short, that recount the reality of the facts as they stand.

The example of vaccines is striking. We brought them forth in a few months, an unthinkable short time. *Perhaps too fast?* Every time, problems alone have been highlighted, usually of an exquisitely technical nature, without the competence to discuss them properly, and without telling the good story, the story of success.

Just let each do their job, and use their skills, as the Extraordinary Commissioner, General Francesco Paolo Figliuolo is doing. Despite the complex problems involved, including some technical problems of our own making, I believe that last year anyone would have gladly paid to see today's total of 55 million administered doses.

Let's be optimistic again, let's be confident again, let's work together.

Ready to compete in building OUR new Italy!

Let's go back to being ITALIANS. We are, I am, and I am proud of it!

ALWAYS!