

THE PRESIDENT'S ADDRESS

ANNUAL PUBLIC ASSEMBLY

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THE WAY WE WERE AND THE WAY WE ARE

At the 2013 Farindustria Annual Public Assembly we said:

"Today we are here because we want to put ourselves to the test with a strong Stability Pact with the institutions, especially those here with us today, by which all commit to be constructive, starting from ourselves. It is a challenge that we sincerely think we can win because we are a vibrant and vital industry, even though we have been going through a serious economic crisis for a long time and especially in our country. A crisis and a challenge that we can overcome if we are allowed to operate in a different context from the current one and considerably different from the former one. In times of crisis, one must not lose heart, but react to the ongoing challenges by enhancing the systems of excellence. "

Only four years have passed since that speech and everything has changed at an unthinkable speed.

Italy was in a deep crisis and the country did not seem as though it would make it. A crisis that made us fear the worst for our industry which back then was hit by the loss of 12,000 employees.

In such a scenario, we asked for an institutional pact for stability and certainty of the rules, thus committing to investment and growth.

The institutions responded. **And we have kept our promises and won together.**

I wish to thank Minister Beatrice Lorenzin, who was then, as she is still today, the Minister of Health; Prime Ministers Letta, Renzi and Gentiloni; all the Ministers; the Italian Medicines Agency (Aifa) and the other respective Authorities who have all made this result possible.

We have lived through these four years with **optimism and passion**, but also with **responsibility and rigour**.

I repeat these words today to all institutions and healthcare stakeholders who are here today. Because that winning Pact needs to be revised now in the light of the very fast **digital revolution** and personalized medicine that are turning the healthcare area into a combination of interactions ranging from **big and smart data** to **ICT** to **sensoristics, physics** and **robotics**.

Managing this phase will be only possible through new **forms of** non-self-referential **collaboration** and a **team spirit** among countries and, nationally, among institutions, industries and healthcare providers. And even among companies themselves.

In fact, without a systemic logic, change will not be able to cope with critical issues, such as the sustainability of incoming new medicines or the protection of personal healthcare data collected on social networks or by wearable devices.

RECOVERY: A RESULT ACHIEVED ALSO THANKS TO OUR COMPANIES

In four years, the country has taken the road to growth, with the symbolically significant surpassing of the "zero point" and GDP growing by 1.3% by the end of the year, according to the International Monetary Fund.

Building on Professor Marco Fortis' economic analysis, we see how the fundamental boost comes from the industry as a whole, which over the past two years has grown more in Italy than in Germany, France and the UK.

And, according to the latest data from Istat (the Italian Institute of Statistics), our companies represent the industrial sector that contributes the most to the growth of **industrial production: + 4.7% in 2017** compared to a national manufacturing average of +0.8%. That, after having grown by 13% between 2010 and 2016, compared to a -5% overall recorded in other sectors.

We have therefore become the protagonists of a long wave of investments in the last decade, starting in production, moving on to R&D and then digital innovation.

As a matter of fact we invested €2.7 billion in 2016 (€1.5 billion in R&D and €1.2 billion in manufacturing) with a **growth of €450 million in the last three years**.

We are one of the great pharmaceutical players in Europe:

- With a **production that is 26% of the total of the big EU countries** and €30 billion, of which **71% is for export**;
- With a leading growth in turnover, exports, added value and competitiveness in the manufacturing sector;
- With **64,000 direct employees; 6,200 of them in R&D** and 66,000 in the upstream sector with **many women** holding significant positions and accounting for over 50% of the researchers.

We are an international hub for medicine and vaccine production, second only to Germany in Europe, and we aim at becoming a continental hub for clinical trials where Italy boasts extraordinary excellences.

This data should be read together with the **growth in productivity** that has overtaken those of the major European countries thanks to the **quality of our human resources**, to the high industrial know-how and to an **innovative, participatory and collaborative industrial relations system**. All factors that, also thanks to the greater stability and certainty of the rules, have made the country attractive for investments.

RESEARCH IS LIFE

But what makes us even prouder as companies, is the decrease in the overall mortality in Italy by 23% in the last 10 years. Specifically, by 33% for cardiovascular diseases, by 35% for respiratory and by 31% for metabolic ones. And by 23% for cancer, while in Europe it is 17%.

We boast enviable records precisely in oncology. According to a recent study by the Swedish Institute for Health Economics, Italy has the highest survivability rate in the continent, the lowest mortality rate and the lowest per capita cost of health care among the Big EU countries.

An Italian success that is the result of the global commitment by the pharmaceutical industry and AIFA itself, but also of an excellent healthcare system with physicians and practitioners of excellence.

Numbers that show extraordinary results due to medicines that are the outcomes of the R&D carried out 10 years ago. What will happen in the next 10 years with the new molecules currently in the pipeline for personalized therapies, gender and women's medicines?

We will simply give **more time to life and more life to time**.

DIGITALIZATION COMPLETELY RESHUFFLES THE CARDS

A study by the Symbola Foundation for Farmindustria shows that Facebook, owner of the world's most popular mass media, does not create content. Alibaba, the largest retailer, does not have an inventory. And Airbnb, the largest hotel provider, has no real estate of its own. Uber, the world's largest taxi company, does not own any vehicles. The Amazon Digital Store is opening "physical" bookshops.

These are some extraordinary examples of how technology today makes it possible to become world leaders with totally new patterns and modes. But will this digital revolution also affect the pharmaceutical industry?

Indeed, it is already part of the daily life of our companies, experiencing this great discontinuity, as evidenced by **digital healthcare investments of €6.5 billion**, that have more than doubled in recent years globally.

Biometric and biomedical data collection through the spread of wearable devices and "confessions" on our social networks, generates 2.5 exabytes of data every day in the world, i.e. 2.5 per 10^{18} .

The genome of a person occupies 4 gigabytes of memory: let's imagine today which extremely powerful "machines" and systems would be necessary to process the data of 60 million Italians.

Genome sequencing costs today as much as a high-end smartphone; while in 2003 the cost of the first full mapping was \$100 million, and it will become just a few dollars in the forthcoming years.

So we are living in a new phase, full of perspectives, which must be experienced with enthusiasm for what it is: a great opportunity to be seized.

Our companies can overcome also this **digital challenge** because they have the talents and the energy they need, and they are already at work with the right toolbox.

BIG AND SMART DATA TO PATIENT HEALTHCARE SERVICE

According to a recent study by Farmindustria with Bain & Company, in the next three years the **pharmaceutical companies** in Italy will gamble in **digitalization** with peaks of **88% in production and 71% in R&D**.

We are therefore facing **a digital revolution of the Research model**.

Smart pills that release the active ingredient only in a specific context or at a precise time are no longer a utopia, as well as those that, taken once a month, release the daily dosage of a medicine every day. Pills working as a vehicle and even capable of exchanging data with the outside world.

Then there is IBM **Watson**. A machine-learning system that **anticipates the future** through a **huge** and constantly updated **database** that compares 700,000 scientific articles, more than 90,000 pathological cases, medical books, industry magazines, data on 10,000 medicines and biological information concerning more than 35,000 genes.

A support both for research activities and for physicians in their diagnosis and indications of pharmacological therapies, always in the strictest respect of the appropriateness of the treatment.

Following the rules of disruptive web innovations, we will have a service app which, with the advice of a physician and according to our clinical history, will remind us

which medical examinations to do and when, at what time the prescribed medicines must be taken and it will also monitor the adherence to the therapy.

MEDICINE: FROM PRODUCT TO PROCESS OF "SOLUTION COMPANIES"

The medicine ultimately blends with services and diagnostics, while **genomics marries the big data** to quickly target **personalized medicine**. Digital technologies redefine the relationship between patients and physicians. The citizen is thus "empowered", i.e. able to interact more consciously and responsibly with their physicians and more generally with the National Health System. In a very strong acceleration scenario, the destiny of the pharmaceutical industry and its role are far from having been written.

Companies will be **increasingly human-centred**, offering patients not just a medicine, but integrated solutions and services that support them throughout their whole life and improve the quality thereof. Within this context, alliances with the chains of robotics, physics and biomedical engineering will become increasingly important. As witnessed by the robots that moving around the home will bring to the patient's bed the right medicines to be taken at the right time.

RULES ADEQUATE TO THE INNOVATION AND THE SPEED OF CHANGE

The sector is clearly at the intersection of technological and digital innovations and the radical transformation of the worldwide research model, which in a continuous vortex revolutionize everything: from corporate organization, to business processes, to the innovation ecosystem.

But in this context for our industry -the most highly-regulated sector - innovating also means having **new rules based on new patterns**, capable of representing the change but also of adapting to it.

For example, adopting the most updated accounting systems. It is a "recipe" indicated by the Ministers of Health of the OECD countries for the "Next Generation of Healthcare Reforms".

Because today's slogan is "speed" and thus overcoming classical learning/training schemes inside the companies that already work according to the 4.0 model and within the public administration itself. Two different realities can start a common path to capture the speed of change that is far higher than that of learning.

Within a few years, professional profiles will be totally different from present ones. So from now onwards we will have to think about joint projects with Trade Unions **to train** young and old people to the professions that will come, **through innovative and flexible approaches**. Besides, we were also the first to have done two things: we have signed a protocol with the Ministry of Labor "Youth Guarantee" and one with the Ministry of Education, University and Research on a major project of alternating school-work training.

HOW MUCH MEDICINES COST AND HOW MUCH THEY CAN HELP SAVE

In this respect, I do not want to side-step the debate on pharmaceutical prices. Even in this case we cannot look to the future with an approach from the past. Does it make sense to ask – as you can hear from various sources - how much has it cost to produce a medicine?

Or is it more meaningful to wonder what it means for the Patients; what savings a medicine can develop for other areas of welfare; how much investment does it generate?

These are questions that make sense today even more so than in the past, both because personalized medicine is growing and because new technologies allow us to measure the outcomes of therapies on individual patients.

So we are facing new challenges for the Italian NHS. The first steps to be taken are the urgent **overall governance reform**, with the re-engineering of a system that needs it, to continue being among the top in the world.

In Italy, we actually have many positive elements such as **the breadth of coverage** in **pharmaceuticals** and the **registers** that allow us to monitor the efficacy of medicines on patients and to access Real World Evidence.

A model that the world envies us, based on collaboration between institutions, patients and physicians; a model in which pharmaceutical companies believe with conviction.

GIVE US NEW GOVERNANCE

Nonetheless, **much remains to be done:**

- on **Access to innovation**, which, although improved, still records regional differentiations and takes a long time, with about 12 months from the EMA authorization compared to the other major European countries, along with regional access times that even double them;
- on the still inadequate **funding for healthcare demand**, as shown by the lowest level of spending among the EU big countries;
- on **overcoming the concept of spending caps** starting from the hospital one;
- on the **protection of intellectual property and investments;**

- on the **uniformity of healthcare policies** across the country, which must be guided by scientific criteria.

With a new governance that improves the competitiveness of our system, our **companies are ready to face the challenge.**

Companies that, I recall, represent in Italy an **extraordinary model**, unique in the world, with the balanced presence of national and multinational companies operating and investing in Italy.

A winning mix that has helped accelerate the innate talents of our researchers and R&D staff. We have companies that know how to invest overseas, from the United States, to South America to the Far East, taking Italian innovation there or acquiring manufacturing facilities and companies. We have companies that are capable of attracting investments from their headquarters thanks to their managers' ability and the skills of highly-qualified researchers and workers; companies that invest in Italy in one of the world's leading vaccine research and production centers; companies that invest in research excellence on advanced therapies, biotech, orphan drugs for rare diseases. They believe in robotics, start-ups and hi-tech incubators; they point to the United States in the strategic plasma-derivative area; companies on the stock market for years in Italy with significant results; companies that get orders from all around the world as contract manufacturers.

And, certainly last but not least, **they have started re-employment** that has grown by over **6,000 employees in the last year, about half of which under the age of thirty.**

THE IMPORTANCE OF COMPETITION AUTHORITIES

But competitiveness also needs general rules such as those relating to antitrust, privacy and transparency. Also here, we have followed new approaches, witnessed for example by our relations with the Antitrust Authority.

President Giovanni Pitruzzella in his Annual Report, after reiterating the need to pay attention to the pharmaceutical sector, has stated:

"(...) **The pharmaceutical industry is making a great contribution to the GDP of the country as well as protecting the health of our citizens.** With this awareness, we have started a closer relationship with AIFA (...) and a more intensive and fruitful dialogue with Farmindustria, with the common objective of spreading a culture of compliance to the competition law. "

Comparison with ANAC (the national anti-corruption authority) and its president, Raffaele Cantone, are fundamental as well, above all, in order to increase even more the already **high commitment to transparency.**

Last, but not least, we must not forget the collaboration with the Italian Data Protection Authority, in order to **implement the new European Regulation** paying particular attention to **clinical trials** and **bio-banks**. An extremely complex and delicate matter, in this phase of personal data explosion on the social networks that requires urgent regulation.

We ask for a competitive environment with a **new Pact with the Institutions** with the same confidence as four years ago. We will certainly be able to do this again together.

We cannot and must not miss the opportunities offered by the possible move of the **EMA** to Milan or by the **Human Technopole**. Both would represent the **engine to speed up the competitiveness** of the Italian System.

In conclusion I would like to say that they call us **Big Pharma**. We do not consider this disrespectful because, actually, "big" we are:

1. Thanks to R&D, we give more time to life: every 4 months we gain 1 month of life and the reduction in mortality in Italy is 23% over 10 years;
2. We have 15,000 new products under development, including 7,000 in the clinical phase;
3. We have customized therapies, advanced therapies, biotech medicines and orphan drugs for rare diseases that are already a reality;
4. We are leaders in production and export;
5. We can be decisive in contributing to the growth of the country thanks to the positive impact on GDP;
6. We are not scared to invest in production, research and development and we have done so as few others have in Italy;
7. We represent job and growth opportunities for our young people in Italy and abroad, thanks to the presence of multinational companies and the internationalization of national ones.

Here is what we mean by Big Pharma: something to be proud of. It is a moment, in many ways exciting, although complex because of the speed of change that requires **optimism, passion and rigour**, but it primarily requires **responsibility and ethics** of responsibility.

We want an Italy that believes in itself, that ride the changes, that is a driver in Europe in the digital challenge, that puts people in the centre, that attracts new international investments and that spreads good scientific culture against the non-scientific.

An Italy that knows how to win and convince.

We believe in this, just like four years ago.

Do you think I have been too positive? Well, I wanted to be and I just want to be Italian.

And I am proud to be so.