

## **SPEECH BY THE PRESIDENT, MASSIMO SCACCABAROZZI**

### **PUBLIC MEETING**

Rome, 4 July 2019

Good morning to you all. I believe that an event such as this always commences with greetings and thanks. However, I would like to make a small break with the tradition of recent years. I would like, first and foremost, to thank and greet the Patients and their Associations present here today in representation of all Italian patients. And after greeting and thanking the Patients, I would like to greet and thank the representatives of Parliament, Government, the Institutions, the Regions, the Public Administration, the Doctors, the Pharmacists, the Judiciary, the Police Forces, the NAS, (the Carabinieri's health and food-fraud units) the Trade Union Organisations and all the healthcare operators and our guests here today.

However, we must not forget our company colleagues or, in particular, the young School/work Alternation students present in the hall for all of whom I sincerely wish a bright future full of success and high hopes.

As early as 2025 we expect to witness innovations so extraordinary as to authorise us to speak of an out-and-out **revolution in how health needs are met.**

And here I must once again address our young participants. Dear boys and girls, a wholly new world awaits you, quite unlike the one in which you lived and are still living.

The frequently acclaimed **centrality of the person**, which we spoke about in the introductory video can really become a practical reality. The levels of physical and psychic well-being of our national community can be dramatically improved.

Such promising objectives have elicited an even more cogent desire to cooperate among all the potential protagonists.

For purposes of this short report I would like to focus primarily upon persons and to speak to persons for persons. So, if we are to speak about persons let's begin with ourselves and allow me to declare - yes, we are ready too!

We are prepared - also by revitalising ourselves - to share methods and know-how with whoever wants to participate in the great project for the common good. Obviously, we want to cooperate with the Institutions, which I thank once again for participating in these proceedings today, but not with them alone.

There are talents, highly gifted persons, skills, as well as public and private structures that through the industry operating in our country are able to accept the worldwide challenge posed by innovation, whose protagonists are no longer limited to the major economies, such as America's and China's, but also include such small and agile countries as Israel and Singapore.

Italy has all the resources necessary to be ranked as a force for innovation.

The **Life Sciences** represent an important part of our universities, our research laboratories, the aptitude of many health structures for clinical trials, and a vital part of our recognised capacity to produce efficiently and to the highest quality standards demanded by the global market.

I mentioned earlier that we often speak about “made in Italy” in the world, but we must not forget that **Italian pharmaceuticals are also made in Italy** and are to be found in every country in the world.

In such a context we can only retain our young researchers by offering them competitive opportunities.

But this will depend upon us alone! Upon the persons present here today: upon our capacity to express forms of leadership, primarily in institutional contexts, that aggregate rather than disaggregate, and upon everybody's willingness to set aside egoisms and expediencies in order to adopt a tightly-regulated standpoint that will allow us to pool our energies and results.

We can really make the sector an engine for production and for that new type of innovation that the Nobel prize-winner Edmund Phelps calls “indigenous innovation”, which will bring new approaches and new methods for satisfying people's needs by ushering in completely new ideas.

We must be insistent as persons and driven by the desire to get ahead.

We must be insistent because our future depends upon us alone. The recent agreement, very responsibly overseen by the government, reached between Farmindustria and the Regions to resolve differences generated by disputed payback figures, may, if it lasts, herald a new phase of cooperation, namely a method of dialogue that eschews unilateral decisions.

Once again we believe that persons are at the centre of all processes. What we have done and will do, has depended and will continue to depend upon ourselves as persons.

The European Medicines Agency (EMA) in its document “**EMA Regulatory Science to 2025**” indicated five actions to prepare ourselves for the future and as we are speaking about 2025 it would be advisable to briefly discuss them:

- 1) catalysing **the integration of science and technology** in medicine development;
- 2) driving **collaborative evidence generation**.
- 3) **Advancing patient-centred access** - once again we are speaking of persons - to medicines in partnership with healthcare systems.
- 4) Addressing emerging health threats and ensuring the **availability of treatment**.
- 5) Enabling and **leveraging research and innovation** in regulatory science

And in point of fact the foregoing indications inspired the title for our meeting.

The revolution under way will lead to ever-more targeted forms of **treatment**, each tailored to individual **persons**. We are speaking of innovations which with a sole dose will, in many cases, cure diseases and change people’s lives for as long as they live. Everybody, I believe, should have access to such innovations regardless of territory or income. Similarly, everybody should be able to access medicines that the doctor and only the doctor - and once again I would like to define the doctor as a person endowed with the necessary skills - considers the most appropriate for each person’s therapy.

**In Italy we have universal national healthcare**, with many outstanding qualities, but which, at the same time, is occasionally asymmetrical as regards the actual guaranteed healthcare levels for the populations in the various regions. This outcome is occasioned by the fact that not all regions have managed to strike the right balance between macro care levels or rationalise the traditional hospital network on the basis of existing indicators and the findings of the national healthcare monitoring programme.

In this context we also find persons with the same rights who have different types of care, different access times and differential access to treatment (or in some cases none at all).

The **sustainability of the National Health Service**, which remains very important to us, will, we believe, depend upon how innovation is managed.

Innovation can and must be a replacement cost rather than an added expense. The epidemiological picture has changed as regards the relationship between the acute and the chronically ill, and in the same way new pharmacological treatment has, in many cases, done away with the need for hospitalisation.

Vision and courage are both needed to create a new, modern re-organisation of the hospital network that will improve services, make spending more efficient and meeting persons' needs as effectively as possible.

We can provide some current examples. If we consider oncology, for instance, many forms of treatment now permit oncological patients to remain outside hospitals, and these, in their turn, produce major savings in terms of sustainability. Similarly, we can consider hepatitis C, about which much has been and will be spoken. However, it is often forgotten that a hepatitis C patient's medical progress used to be predetermined: whoever had the disease invariably encountered, without today's treatment, cirrhosis, carcinoma and a transplant. Every year, Italy spent one billion on hepatitis C. In view of the fact that today about 185 thousand patients have recovered from hepatitis C we can appreciate the extent of the savings made. 185 thousand persons no longer require a support allowance and hence medicines can, in these terms, also play an important role.

Also take a disease such as HIV, which a few decades ago was deemed incurable. Previously, a person afflicted by HIV seeking a doctor's help was informed that he or she had little chance of survival. Today's HIV patient, in the hands of a doctor, has a life expectancy higher than a patient with diabetes. And this clearly means that the question has now become one of chronicity.

In this respect we must express great appreciation for those regions that have already approved chronicity programmes.

By now throughout Europe, the issue of pharmacological treatment is an integral part of healthcare processes. This requires a strong and urgent commitment to re-engineer our health systems.

Financial sustainability must be part and parcel of health sustainability in terms of **appropriateness and an integrated health and social service** .

Reorganisation will generate major savings whereas the proposal to make cut backs on NHS medicines will only produce "micro" savings that may potentially come into conflict with the need to make suitable therapeutic solutions available.

And above all, if we are speaking here of medicines that at the cost of a **few euro per month** help many persons affected by serious pathologies.

**New therapies** not only **transform** healthcare, but also **the behaviour** and the habits **of persons and communities**, and therefore, of society at large.

Spending on **health is an investment** that benefits both persons and the nation.

We are quite prepared to discuss the sustainability of new therapies if we mean **Value-Based Healthcare** remuneration schemes where payment for therapies depends upon the benefit accruing to a patient; and where the state and regions are willing to calculate the cost savings obtained in services in order to implement the rationalisations we have been speaking about.

This is what we mean by replacement rather than added spending.

**Innovative models** such as those studied throughout Europe, the so-called **Novel payment models**, are needed and here Italy is taking a pioneering role.

I would like to give an example based on conditional reimbursement models. Having introduced 100 such models, based on the foregoing types of contract, Italy is the world leader with 35% of such models, while the United States, at 24%, comes in a distant second. The other European countries of the same importance as Italy represent no more than 5%.

In conclusion, it is necessary to **construct a holistic system centred on the patient that does away with** the current “silos” mentality. A system, therefore, based upon an **interconnected healthcare model** where results are measured over an entire diagnostic, therapeutic and care path, and account is taken of the **costs saved by medicines** or by any other health technology on condition that other health or social welfare type costs are avoided.

But without the necessary **flexibility in the rules**, to be “tailor-made” for this ongoing and rapidly developing context, we shall be sidelined by international competition.

However, as persons working in the industry, as persons afflicted by illness, or as persons living in this country, we do not want to be sidelined.

At the global level, R&D accounts for **16 thousand products under development**. The number of highly complex medicines, designed for example to treat cancer and rare diseases are constantly increasing.

Today it is common to speak about personalised medicine, which means that R&D is also personalised. **Personalised** medicines account for over **40%** overall, and **almost 70% in oncology**.

Similarly, **Next-Generation Biotherapeutics**, such as cell, gene and nucleotide therapies, which having doubled over the last three years, are clearly on the increase.

We must be prepared and ready, we cannot permit ourselves to arrive unprepared. Do you know what is arriving?

Something that will change the world and people's lives.

**Very promising therapies** will be available in the coming five years: **CAR-T**, based upon cells genetically modified to combat blood cancer; **combination therapies**, based on the action of various types of oncological treatment; other **gene therapies** to replace defective or missing genes for the treatment of genetic diseases and **tissue therapies** that regenerate damaged tissue by restoring their functionality; **innovative antibacterial treatment**, designed to attack bacteria in an even more selective manner than before and combat infections as well as the now worldwide phenomenon of antimicrobial resistance (AMR).

I stated earlier that in many cases a single dose can change people's lives.

But this is not all.

Thanks to **digital therapeutics** our present is already increasingly tinged by the future. Digital technology is changing not only our life but also the lives of persons in general and the manner in which therapies are performed.

**Digital therapeutics** are a reality, especially digital therapies based on software used in combination with medicines: some have already been approved in the last two years by the USA's Food and Drug Administration.

Between 2014 and 2018, **an average of 46 new medicinal products** per year were approved worldwide.

In the preceding five-year period **the annual approval rate was 36** .

In the next five years **it will be 54**.

There will be new medicines enabling us to cut healthcare-related costs by reducing the number of hospital admissions and preventing or slowing down the progression of pathologies.

In this manner the medicinal product, hitherto a simple product, can become part of an **interconnected process, including R&D**, in association with devices, diagnostics, medtech and caregiving. This is the so-called **Connecting Healthcare**.

**Digitalisation** is revolutionising the collection, **analysis and integration of patient data** yielding considerable benefits in terms of efficacy and improvements in performance as regards both efficiency and process governance.

Just think of the possibilities this will open up for the elderly, for whom monitoring can take place through **telemedicine**, or for **hospitalised children**, who can remain in constant contact with their families or friends. Similarly, diagnostic tests can be made more precise, and systems introduced to improve **adherence to therapy**.

I would like to provide a small example of what we are doing, and apparently one of little moment. It is not on a par with new cell therapies yet it is, nevertheless, important. Imagine, for example, smart blisters that guarantee adherence therapy because every time a pill is removed from the blister a signal is emitted to indicate that the medicine has been taken. And this is important because we know that adherence to therapy produces major savings by avoiding relapses and hospitalisation and therefore, also in this case, the use of medicinal products in situations of chronicity can produce savings in other sectors.

Individual persons will principally benefit from digitalisation and not least thanks to better **doctor-patient and doctor to doctor communication**. In other words, from doctor to patient, and from doctor to doctor: a communication between persons.

Thus, primary-care information flows, as also activities involved when patients are taken on, will be optimised while at the same time the continuity of healthcare will be guaranteed.

However, such benefits must be complemented by a correct and rigorous observation of privacy in compliance with current legal requirements. This is a fundamental question and one already being studied by the competent authorities in this country and internationally.

As I mentioned we would like to contribute towards seizing the opportunities offered by **Crashing innovation**.

Precisely for this reason we deemed it appropriate to initiate a dialogue with the institutions, as we have always done in the past, and for whose functions and role we have a profound respect. Our desire has always been to represent the legitimate interests of our companies with solid arguments and through a dialogue based on practical proposals. In other words with rigour, transparency and the establishment of shared solutions.

We have already mentioned the major achievement obtained thanks to a meeting with the Health Ministry and the regions for a **€ 2.4 billion pay-back** payment, in other words the extent of pharmaceutical over-spending with respect to the FSN's (the national health budget's) programmed expenditure ceilings for the years 2013-2017.

It should be borne in mind that this sum is in addition to the 3.8 billion returned by the companies to the NHS, in compliance with the negotiated agreements based upon the aforementioned clinical outcomes, namely the 35% of those contractual

models in place in Italy and accounting for our world leadership in this field. And, it should be remembered that these are negotiated agreements, which, in their turn, are based on the sharing of risk and therapeutic success.

Such an enormous sum bears witness to a clear per-capita under-funding of public pharmaceutical spending in Italy, which is still over 25% lower than the average amount spent by the big European nations.

Consequently, how can it be argued that several billions were overspent when it is precisely this amount that is missing? We firmly believe that such under-funding must, in some way, be remedied by ceasing to group expenditures into identifiable “silos” for budgetary control and, instead, by considering healthcare spending in its totality and putting the patient at its centre.

Prices are often mentioned but it is always forgotten that the foregoing figures, insofar as repayments, mean that the prices actually paid are much lower than those published.

I can give you an example. Recently, I participated in an event in which the price of a certain medicinal product deemed to be too high. The price of the medicinal product in question was the one stated in the sales invoices. My reply to this comment was: “Yes, but on the other hand there are credit notes and credit notes serve the purpose of returning money, and they should be taken into account as they impact upon a medicinal product’s price”. I was a little shocked by the reply as it seemed something akin to an untruth. My interlocutor retorted: “But, I see the price stated in the invoices” to which I replied “Well, I see the prices stated in the credit notes and thus if I disregard invoices and only see credit notes, it would mean that that the medicinal product is not only a gift but also that its use is being paid for by us”.

I believe that it is important not to ignore this truth.

Putting persons at the centre also means making **adequate resources** available to avoid problems of access to appropriate healthcare. There are forms of care that must guarantee patients all alternative therapies based on **criteria laid down at the national level**.

As entrepreneurs and managers of national companies under Italian or foreign ownership, we have put an end to the season of claims and appeals by taking a **voluntary initiative in a spirit of convinced and responsible cooperation**.

We also appreciated that the recent annual report by the Court of Auditors on healthcare expenditure highlighted this agreement.



As an Association we have interpreted the function of representing our members' interests in an innovative manner, namely by ceasing to follow up individual needs and by jointly attempting to find an overall approach for both companies and Institutions.

Thus, I would like to sincerely thank all the colleagues and persons at work in **our companies** whose outstanding commitment has made it possible to achieve this objective. These thanks are truly heartfelt because I consider the Agreement an important step forward that not only ourselves but the entire country has been expecting for years.

Respect for the Agreement requests loyalty. However, I must add that, albeit not an easy task, we are complying with the Agreement reached with national and regional institutions, to whom we extend our thanks, as **responsible persons and companies**, who have put their trust in a new governance of healthcare that will interpret the new scenario and the new questions at issue.

Let me emphasise the word new.

The Agreement lays down that we move forward on discussions on many open questions: the new pharmaceutical governance, adequate resources, the confirmation of funds for innovative medicines, equal access to therapies over the entire national territory, the safeguarding of patents and the value of trademarks and the recognition of our industrial role.

And clearly it is necessary that all **choices** should be **scientifically grounded**, as this does not usually happen, and **no longer based upon purely economic criteria**.

We want to carry this second part of the Agreement forward with the same efficacy and conviction as we did for the first part.

We are ready to do our part as we are certain the Minister of Health, Giulia Grillo, will do hers, and to whom I would like to extend my thanks for being here today, as I believe that her presence is important especially for the persons I referred to earlier, namely the sick. It constitutes an important gesture because the Minister and all the national and regional institutions present here today are predisposed to believe, as we do, that the future of healthcare can be governed by **persons** such as ourselves, and for the **persons** who are still waiting.

We are facing up to the **competition** intrinsic to the technological and scientific transformations taking place with the will to demonstrate just what our country can achieve.

We provide quality employment, especially for the young and for women; we “produce” health and longevity; we are committed to sustain the needs and aspiration of our employees with ever-greater corporate welfare measures.

This is the **companies' real social responsibility**. We do not reduce labour relations to a perfunctory exchange between performance and remuneration because we view the **persons** who work with us in their entirety - and here again I would like to emphasise the word persons - by helping them manage their needs in terms of health, prevention and assistance to family members.

This objective has also been reached thanks to industrial relations with the friends of the trade union organisations present here today, and who I would like to greet and thank for always being proactive and constructive.

**We are convinced that our industry constitutes a vital force** for the economy as whole because the incremental increases it has recorded in employment, investment, exports and production are unparalleled in recent Italian history.

And also in terms of our contributions: as a sector we bear a special tax rate because we are an industry, and like all industries are subject to tax. However, in addition, we also have to shoulder pay-back payments, which can be construed as an additional tax.

In 2018, pharmaceutical companies made **important investments in our country** because, aside from the billions in pay-back payments, a sum of 3 billion was altogether made available for investments; one of the pillars of R&D.

With 1.7 billion euro in 2018 alone, pharmaceutical companies, as a sector, rank first in terms of investments in innovation per employee. These investments, at 3 times the national average, have produced excellences in biotech medicinal products, blood derivatives, advanced therapies, vaccines, orphan medicines and clinical trials.

**We are a productive hub in Europe** and create industrial and scientific value in association with the public centres with which we conduct research of excellence. In short, we represent a fundamental part of Italian and European industrial culture.

We are aware of the responsibility that this represents and are ready to be continuously monitored in terms of healthcare outcomes, the quality and quantity of the work produced, and the contribution we make towards furthering the nation's prosperity.

We simply request shared rules in the framework of a collaborative relationship that respects the participants' different roles. **Lasting, fixed and mandatory rules**; lasting rules that allow us to produce those industrial plans that do so much good for our nation and thus to the persons within it.

**Let us discuss a new governance model together.** We shall put the right skills on the table along with models made by persons for persons; in fact, the self-same persons who, with a great sense of responsibility, managed previous models.

We firmly believe, given what is arriving and what is new today, that the old models based upon “everything remains unchanged” will not enable us achieve the objectives we have set ourselves.

Our skills must address new scenarios not derive from old models.

The world is changing and has changed. Even our own models are already out-of-date. Therefore, averring that everything remains unchanged is a denial of R&D. And there are many researchers here.

And I believe there is one important thing that behoves all researchers: to **valorise** and not belittle **differences** by saying that nothing has changed.

We have always said that these models are out-of-date. However, if we really believe that they represent the solution, allow me to refer to them with their true name: not solution but **utopia**.

Do we really believe that old recipes dating back dozens of years and found to be wholly useless in the past, as in the present, can be of any help?

And do we really believe that measures levied on medicinal products for a couple of euros a month can produce billions and billions in savings when the patents on 90% of the medicinal products in the territory have expired?

I do not believe that this is credible and we do not believe that this is the solution. Instead, we believe that one thing should be done. We must attempt to work something out together and in doing so jointly we shall grow together. We are not in competition with one another.

**We want to prevent one of the remaining sectors driving the economy from being destroyed** because our house is in order.

This is an important question for us and therefore allow me to suggest that we should work together and never forget that if we are to give life more time and time more life, at the end of the road we must travel down “together” there will always be a person.

A person whom we call a patient, a person that needs us to consider him/her as a person, a person we should put at the centre because these are the persons who are waiting. And they are awaiting the results of our work.



And if together, without prejudices, with transparency and the desire to succeed, we do succeed in implementing the right solutions we shall have performed a long-awaited service for all persons in this country suffering from ill health!

Thank you for your attention!!