

INFARMED's 30th anniversary

17th January 2023

President of INFARMED

Rui Santos Ivo

Speech

S. E. the President of the Republic, Prof. Marcelo Rebelo de Sousa,

The Portuguese Minister of Health, Mr. Manuel Pizarro,

The Secretary of State for Health Promotion, Ms. Margarida Tavares,

The Secretary of State for Health, Mr. Ricardo Mestre,

Your Excellency, Chief of Civil Staff of the President of the Republic, Madam Consultant for Health and
Madam Secretary of the Council of State,

Honourable Members, Members of the Health Commission of the Portuguese Parliament

Director-General of Health, Mrs. Graça Freitas,

Executive Director of the National Health Service, Prof. Fernando Araújo,

Dear Colleagues who are leaders of the Ministry of Health and Public Administration :SGS, IGAS, INSA, SICAD, INEM, SPMS, ACSS and ARS's, ANEPC, ASAE, AdC, AICEP, DGAE, IAPMEI, DGAV, AT, NCAMS, SUCH, AICIB, LNM, IPST

Dear Presidents, representatives of the Professional Associations and leaders of the associations of INFARMED's regulatory sectors in the area of medicine, medical devices and cosmetics,

Dear Members of the Association of People with Illnesses and Association of Consumer Protection,

A warm welcome to universities, research centres, health units. INFARMED has in its DNA the collaboration with all these areas of science,

My dear colleagues, INFARMED's Board of Directors Carlos and Érica,

A warm welcome to the presidents of INFARMED's specialised technical committees: CAM, CATS, CNFT, CFP,

Greetings to our colleagues who are members of the Workers' Commission,

And to our colleagues on the Board of the INFARMED Club,

As well as

To our colleagues' directors of the various Departments and Units of INFARMED, as well as all the colleagues who follow us in streaming in the rooms on the upper floor,

A special greeting to the several former members of the Government in the area of Health who in different periods held office, Minister Luís Filipe Pereira, Secretaries of State Jorge Pires, Francisco Ramos, Carlos Martins, Manuel Delgado, António Lacerda Sales and Diogo Serras Lopes,

Dear former presidents and other members of INFARMED's Board of Directors

I warmly welcome Dr. Aranda da Silva, the first president of INFARMED and who brought me here as early as 1993 - 30 years ago as well.

But also, my colleagues Vasco Maria, Hélder Mota Filipe and Maria do Céu Machado with whom I also had the privilege of working with in the past.

A very warm welcome to all of you.

Dear colleagues,

I would like to extend a special welcome to several former colleagues who are here today, from the most recent to the oldest - please allow me to mention them because I know that Isabel Abreu and Fátima Neutel are here, and through them I would like to greet everyone else in a moment to symbolise our homage to all those who have recently left INFARMED.

Ladies and Gentlemen

Dear friends,

Friday 15 January 1993. The Diário da República nº 12 of 1993 publishes in its series I-A Decree-Law nº 10/93 the approval of the organic law of the Ministry of Health, creating the National Pharmacy and Medicines Institute, INFARMED. Now known as the National Authority for Medicines and Health Products.

INFARMED is created 8 years after our entry into what is now the European Union and in the same year in which the European Agency for the Evaluation of Medicinal Products is created, which came into operation in 1995. This was undoubtedly essential to our capacity building in the area of medicines and other health technologies, both at national and European level.

Three decades later, it is an honour to receive you today for the commemoration of INFARMED's 30th anniversary, either in person or virtually, enabling us to reach all those who wish to accompany us, beyond geographical and space limitations.

The Board of Directors and INFARMED as a whole would like to thank His Excellency the President of the Republic for joining us on this day and honouring us with his presence at the inaugural session of our celebrations, and also for having granted us his high patronage. It is for all of us the recognition of the activity that takes place in this institution, every day, for the benefit of our fellow citizens and representing our country. Thus, this has an enormous significance in terms of responding to the expectations and needs of future development for a greater performance of our mission. Our heartfelt welcome, Mr. President.

We are also very grateful to the Minister of Health for being here and for being part of this day of celebration at INFARMED. We feel that his presence is the support and recognition of our work for the protection of health and in response to the needs of our health system and citizens.

A special thank you to our distinguished speakers here today who give us the honour and privilege to share their experiences, knowledge and perspectives on current and future challenges concerning medicines and medical devices.

Lastly, I would like to express my deepest and most heartfelt gratitude to my colleagues at INFARMED who have contributed to these thirty years of such a historical path. Today, there are more than 300 professionals who work every day so that INFARMED can fulfil its role, so that in the end, health professionals and citizens can keep their confidence in the technologies and health products that they prescribe, dispense and use.

Dear colleagues, each one of you, regardless of your career or position, represents an essential contribution to INFARMED's 30-year anniversary. It is your talent, excellence, scientific rigour, knowledge and performance, in INFARMED and in the European bodies that enables us to fulfil our mission and to have INFARMED's competencies recognised both in the national as well as the European context. Portugal and INFARMED are proud of you. Thank you very much.

Over the past 30 years, INFARMED's staff, some of whom are present here today, have participated in many pioneering national and European scientific and regulatory initiatives, which culminate in the prestige of our experts in various fields of knowledge. Today, it is important to celebrate the past, in order to look to the future. Therefore, I would like to highlight some of the milestones that have contributed to the consolidation of our National Authority:

- i. In the 1990s, when INFARMED was founded, we sought to be an institution that was ahead of its time by assuming digitalisation as a priority goal, the immediate participation of national experts as important players in the European Medicines Agency (EMA) and in the evaluation of the cost-effectiveness of medicines, being the first country to publish methodological guidelines for studies on the economic evaluation of medicines.
- ii. This was followed by a phase of strong consolidation at national and international level. It started with our work for our Quality Control Laboratory and the regulation of activities inherent to generic drugs, such as their reimbursement and the generalisation of prescriptions by INN. Another highlight was the public release of INFOMED, our database of medicines. Additionally,

- the construction of the National Pharmacovigilance System, the creation of the Ethics Committee for Clinical Research and the publication of the 2nd Medicines Statute which was instrumental in preparing INFARMED and the health sector for the years to come.
- iii. In the following decade, the creation of the National Pharmacy and Therapeutics Commission), the National Health Technology Assessment System (SiNATS), as well as INCLUIR, a project involving people with illnesses, in order to guarantee equitable and sustainable access to new therapies, should be highlighted. At the level of medical devices, I would highlight the consolidation of their codification process and, in the area of clinical and translational research and medical innovation, the constitution of the Agency for Clinical Research and Biomedical Innovation with INFARMED as one of the founding partners.
- iv. More recently, INFARMED, was well known to all, due to the management of the COVID-19 pandemic, at national and European level. This was a moment of great advances in the evaluation of health technologies and the development of strategies in the area of availability of medicines to combat shortages and ruptures. Since 2019 a very solid work has been pursued to act in this area, with the amendment of legislation, the creation of a dedicated unit at INFARMED in 2021, the institution of the Monitoring reaching industry, distributors, pharmacies, health units, health professionals and patients. In addition, we have created the conditions for extending the EMA's Mandate during our Presidency in 2021 and today we, the European bodies, the EMA and the national authorities, are working on a rigorous and systematic strategy to act on this issue, from the causes to the consequences. We also have an important partner, which is the CNFT, and with the Ministry of Health - and the Minister has referred to this issue - we are supporting intervention at other levels.

Before moving forward, allow me to publicly thank the European Commission's Director-General for Health, Sandra Gallina, who is here today, for the work she has done with the Member States, whether on the European Vaccination Strategy and access to vaccines for COVID-19, or on the actions to develop a European Health Union, which will have new initiatives this year.

I would also like to publicly thank the Executive Director of the European Medicines Agency, Emer Cooke, who is also here today, for the support and availability she has always shown to Portugal and for her daily work and collaboration with all the national agencies. It was a remarkable example of dedication and cooperation.

And of course, an equally special thanks to my colleague Maria Lamas, Director of our Spanish counterpart. Our close, complicit bond and strong collaboration allowed a relevant European participation and the response to operational problems, such as the availability of medicines and the joint procurement of vaccines.

Additionally, I would like to mention how the close collaboration between the various national institutions was fundamental: in the Ministry of Health, the DGS, the INSA, the ACSS, the SPMS, INEM, SICAD, ARSs, health units and in other Ministries, the AT, the ASAE, the DGAE and several Universities. Such collaboration resulted in a collective force, essential to the national response to the pandemic. This articulation was "natural" and therefore efficient, because it was based on a history of institutional cooperation of which INFARMED is proud since its origins, often being a partner, promoter and leader. This collaboration was extended to the various economic sectors so essential in the fight against the pandemic.

At the beginning of the last decade, and in a highly demanding context, we assumed the Portuguese Presidency of the European Health Policy. We should highlight the success of the approval of the new European Regulation on Health Technology Assessment, the work carried out to create a European Health Union, which will strengthen the European Medicines Agency with regard to monitoring the activity of health technologies, responding to emergency situations and consolidating the proposals for the Pharmaceutical Strategy for Europe. The latter, charts a path towards a new European regulatory framework for the future, as Director-General Sandra Gallina will present shortly.

INFARMED's daily activity, in its various competencies and areas of intervention, continues to translate into the protection of public health. We guarantee the safety, quality, efficacy, accessibility, availability, cost-effectiveness and correct use of health technologies. We are key players in promoting national economic competitiveness, through the growth of national industry and clinical research in Portugal.

It would be impossible in a speech such as this to detail the scope and diversity of interventions that INFARMED has been called upon to perform over its 30 years of history, and particularly in the last three years marked by a crisis, but I must stress that this was and is only possible due to the capacity, resilience and prompt availability of our staff. There are countless examples of this, and history will take care of highlighting them.

And 30 years have passed...

Let us now look into the future. Technical, scientific and technological advances, in the chemical, biological, medical, pharmaceutical and information technology fields will drive a new reality in therapeutic innovation and the regulation of health technologies. Allow me to highlight some of the challenges:

- i. Artificial intelligence and the use of real-life data are challenges to which INFARMED is attentive and present, an example of which is our integration in the European Project Real4Reg.
- ii. The emergence of new realities in therapy and diagnosis, with the advances in gene therapy, which mean more demanding evaluation, surveillance and monitoring of health technologies.
- iii. The pursuit of a health technology assessment system, with common assessment methodologies and processes in Europe, will guarantee the population's equitable and timely access to health technologies and interventions. INFARMED is at the forefront of its definition, even taking on the leadership of the respective European structures
- iv. The increasing complexity of the production and distribution chains and their vulnerabilities require cooperative action at the European level.

As we will hear it today, there are challenges ahead.

Let us start with the Health Technology Assessment legislation that has its new European regulatory framework fully applicable in 2025!

The Medical Devices Regulations that will change the existing framework by 2030.

The new Clinical Trials Portal that creates a mandatory single European gateway as of 1 February 2023.

The future new European Health Data Space and all the future it opens.

The major structural change in pharmaceutical legislation whose reform the Commission will present this quarter and about which Director General Sandra Gallina will also tell us.

Furthermore, we have changes at a national level in our health system as well as at the level of research structures, universities, research centres, health units.

INFARMED is heading towards the future and needs the appropriate instruments to make this path. A path that requires the capacity to respond in our country and also within the framework of the European network of drug authorities.

Just as at the beginning of this century it was necessary to adapt the organic structure, the conditions and the technological and financial resources to the strategy designed at the time to achieve national and European goals, it is now time to update INFARMED's regulation and governance model so that we can respond to the technological and scientific challenges we are already experiencing.

It is therefore urgent to promote a framework that allows for better retention of professionals and the strengthening of teams, reaffirming here, before our Minister, our commitment and commitment to find solutions to overcome the challenges faced by INFARMED in terms of human resources, ensuring the creation of attractive conditions that reduce the impact of competition on recruitment by the regulated sectors.

Our response is not compatible with processes that require chain authorisations, which are time-consuming and not in line with the needs and response times.

INFARMED has the means and takes full responsibility in managing them.

It needs the tools to access the resources and to manage them in order to respond to the different needs, at a technical and scientific level, to assess the cost-effectiveness of the technologies and their financing conditions, to monitor their conditions of use, and to ensure the sustainability of the National Health Service.

We are looking forward to the future. We benefit from the experience and maturity of these 30 years of life and experience, which we want to translate into a new status, a strengthened status for INFARMED as a regulator in all its areas of competence. INFARMED is committed to creating solutions in order to keep up with the evolution of new fields of knowledge and to strengthen Portugal's prestige, nationally and internationally.

We need a statute with more autonomy, but at the same time with more responsibility, one that is essential for our staff and for the new future we are building.

Finally, we will have several moments of celebration of this 30th anniversary throughout the year, which will cover themes related to the several areas we intervene.

Allow me to finish this speech by reminding you that INFARMED is its people. Congratulations for being a reference organisation.

Congratulations INFARMED.