

MINISTÉRIO da SAÚDE
Gabinete do Ministro



Portugal em Acção

1º IBERIAN GENERIC MEDICINES MEETING

Minister
Luís Filipe Pereira

Infarmed
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APOGEN

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- Mr. President of APOGEN, Mr. Joao Felix
- Mr. Director General of the European Generic Association (EGA) – Mr. Greg Perry;
- Madame. Director of the Spanish Medicines Agency, Mrs. Maria del Val Diez Rodrigálvarez;
- Mr. Representative of the Directorate-General for Competition in the European Commission – Dr. Abraão de Carvalho;
- Mr. President of the Spanish Generic Medicines Association (AESEG) – Mr. Guillermo Tena;
- Mr. President of the INFARMED, Dr. Rui Ivo, host of this Iberian Meeting;
- Honourable Chairmen

Members of Parliament;

Ladies and Gentlemen

I would like to start by congratulating **APOGEN** and the **EGA** for organising this **1st Iberian Meeting on Generic Medicines**. It is a great pleasure to participate in the opening session of this event.

The importance of the topic and the level of the speakers would alone justify this gathering. However, in my belief, it is increasingly important to cement cooperation between member states in healthcare policies.

In a global context, in which the pharmaceutical industry defines strategies at worldwide, European and local levels, it is fundamental that national health authorities have the same capacity to act to the same degree.

More and more, decisions made in one country, by a competent national authority, affect the policies of the remaining states. For this reason, only through strong international cooperation can a country decide which policy best protects its citizens, while also protecting the citizens of the remaining countries.

Therefore, I hope this will be the first of many other meetings which are bound to follow and which will surely help to build cooperation in medicine policies between individual countries and in the context of the European Community.

The XVI Constitutional Government assumed and has reconfirmed a commitment to the Portuguese people: *to implement real healthcare reform in Portugal, through a healthcare policy dedicated to the service of the people, guided by a concern to provide patients with quality care, in a timely, efficient and humane manner.*

The underlying principle of the structural reform underway in the healthcare area in Portugal is to restructure the sector, aimed at meeting the needs of citizens' welfare and at facing five major challenges for which an efficient solution is needed, that is:

- the challenge of maintaining a level of quality already permanently assumed;
- the improvement of patient accessibility;
- a timely and humane response;
- greater efficiency and rigour in the use of available resources;
- the financial sustainability of the system.

These objectives are essential in order to attain more and better healthcare for the population. This is why thorough reforms were introduced in the various sectors of the SNS (NHS)-Serviço Nacional de Saúde (National Health Service) – having as the ultimate beneficiary the citizen.

In these circumstances, since the previous government, we have prepared and defined a real **Medicines Policy**.

We have elaborated a “Package” of measures, essentially aimed at patients, in which the following were established:

- Compulsory prescription by International Non-propriety Name (INN) when generics exist;
- Promotion of the use of **Generic Medicines**, which are always much less expensive, costing at least 35% less than brand name originals;
- Adoption of **Reference Prices**, ie, a new reimbursement system incorporate generic medicines into homogenous groups;
- Creation of a **Standard Prescription Model**, and a **Renewable Prescription** for chronic patients; and also
- Transfer of the so-called “**copy-cat**” medicines to generic medicines.

No other government has managed so far to drive a **Medicines Policy** and the promotion of the use of **Generics**.

Nevertheless, the situation of Portugal with, on the one hand, the highest medicines consumption per GDP and, on the other, the smallest generic market share, made it essential for Portugal to take these measures if it was to continue to be a Member of the European Union.

In fact, the development of generic markets was defined as a legislative priority in the XV and XVI programs of the Constitutional Governments.

This was, and still is, a priority because we believe that it is a decisive means to ensure accessibility of citizens – particularly of deprived citizens – to less expensive medicines which have the same therapeutic value while simultaneously allowing for cost containment in the NHS on medicines and contributing to ensure its financial sustainability.

In the current social context of increased life expectancy and an aging population, the Medicines Policy adopted has helped to provide people, especially those who are more vulnerable and in need, with an alternative in the use of medicines that did not exist before.

These were the reasons we undertook to implement a set of measures in the medicines sector with the objective of promoting the Generics Market as soon as we came to office.

The results are visible.

I believe that today it is unanimous that the Medicines Policy in Portugal is a success.

In fact, the latest indicators available on the current situation in Portugal clearly show the fairness in the measures taken by the government.

As it is well known, the NHS expenditure on medicines is and always has been increasing, but in the last 2 years it has been possible to control this expenditure to values much lower than the average registered between 1996 and 2001.

It is worth mentioning that the growth in spending from the NHS in medicines, in retail values, was at 10% in 2000 (versus 1999); and 10,4% in 2001 (versus 2000), decreasing to 7% in 2002, and to 3,7% in 2003. This was the lowest value ever.

In 2004 the value will most probably be higher than in 2003, which, as I said, was the lowest value ever, due to the fact of a higher number of new medicines now being reimbursed by the NHS and by the larger number of visits and surgeries performed.

With the objective of giving continuity to the adopted Medicines Policy, a set of measures are being put in place which aim to reinforce the commitment of the Government to promoting generics as a means to control the NHS expenditure and, at the same time, to promote the rational use of medicines.

Therefore, I would like to highlight some of those measures here today.

Let us look first at the beginning of the activity of the CURM - Comissão para o Uso Racional do Medicamento (Commission for the rational use of medicines).

CURM's objective is to promote the rational use of medicines by all relevant stakeholders. This objective is particularly important when taking into account the national context of the use of medicines.

Secondly, we are finalising the project for dissolving the prescription and implementing the electronic prescription, which should start its pilot phase in January 2005. This project will start in Portalegre and will then be progressively adopted throughout the country during 2005.

We are confident that this process will introduce much greater efficiency in the medicines circuit, allowing for easy and well-informed prescribing which will benefit both the doctor and the patient.

Another measure that I can also announce to you is the launch of a new information campaign dedicated to promoting generic medicines.

As of yesterday, two new TV adverts are being run with the objective of informing and reinforcing patients' trust in medicines in general and in the generic medicines in particular.

We trust generics. It is important that the people trust them too.

To ensure the success of the strategies defined by the Government in this area, we need the support of all stakeholders in the healthcare sector: doctors, pharmacists, pharmaceutical industry, and of course, patients.

I believe the doctor and the pharmacist have progressively shown their support to our policy.

It is not only the obvious increase in prescribing that reflects this support, but also other indicators, such as the interest and increasing use of the information sessions which INFARMED has been developing throughout the country, the increase in visits by doctors

and pharmacists to the INFARMED laboratory, the constant requests for the generics guidebook and the therapeutic use guide, and the increase in access to INFARMED's medicines database.

Another aspect that I would like to draw the attention of the Pharmaceutical industry to is related to the introduction of new active substances to the generics market.

The potential market development of generics is dependent on the creation of new homogenous groups. Not only through the introduction of new presentations or pharmaceutical forms, but above all through new active substances.

The market segments where it is possible to create new homogenous groups have not been fully explored. There are more than 50 active substances that will lose their patent protection by 2007, and about 50% of reimbursed active substances marketed at present will no longer be protected by patent.

This presents opportunities for the commercialisation of generics, and is surely a way to encourage and increase the generics market.

The generics policies also aim at rationalising and managing existing financial resources in the best way possible. The savings generated at the NHS have allowed governments to apply these resources to other measures, namely to the reimbursement of innovative medicines and to the support of chronic diseases.

The number of reimbursed active substances since 2002 (79 new active substances) shows the dedication of the government to improving patient access to therapeutic innovation.

It is clear, as I said, that the increase in the number of reimbursed medicines has accelerated the growth rate of medicines expenditure, which was made worse by the fact that some of these medicines are among the 20 most sold medicines.

Our main priority is to obtain health benefits for the most disabling diseases, in this way ensuring greater access of needy patients to medicines.

Recent data on generic medicines from October of this year register very pleasing results as we have reached a **market share of over 9%** – 9.1% to be exact.

This represents a market share of 0,3% in 2001, evolving to 1,76% at the end of 2002 and to over 9% before the end of 2004.

The number of authorised generic medicines with approved prices in Portugal in October 2004 stands at 1,252, which is equivalent to 3,424 different presentation forms. This represents an increase of 80% compared to October 2003 (analogous period).

It is important to stress other key facts here, which underscore the success of the measures taken despite scepticism of many:

- Before all, it is important to say – loud and clear – that this policy has benefited both the patient and the State;
- These savings reflect a dual aspect: an increase in the consumption of generics and the repercussion of the decrease in prices of branded products;
- With the implementation of the reference prices, came an obvious general

decrease in the prices of branded products where generics existed, showing in some cases reductions of more than 50%.

We must not underestimate this success of our efforts nor the advantages gained by the Portuguese people. The European Generic Medicines Association looks at the Portuguese example as a “case study” and follows its evolution eagerly.

I wish you all a very productive day of work, and hope to meet with you again to continue sharing some of the changes that are the result of the Structural Reform taking place in the Portuguese Health Sector.

Thank you very much.