

AESGP MEMBERS' MEETING

IMPACT OF THE POLITICAL AND LEGAL DEVELOPMENTS IN EUROPE ON THE PHARMACEUTICAL LEGISLATION FOR NON-PRESCRIPTION MEDICINES AT NATIONAL LEVEL

Claudio Lepori. President, anefp. 4th February 2009

AGENDA

- 1.- Anefp, the Spanish Association of self-care Industry**
- 2.- Spanish EFP market 2008**
- 3.- Spanish Legal Framework for Pharmaceuticals**
 - Before new Medicines Law
 - Currently (Transposition on Community Code of Medicines into Spanish Legislation)
- 4.- Some words on advertising of EFP medicines**
- 5.- Hopes for the future**

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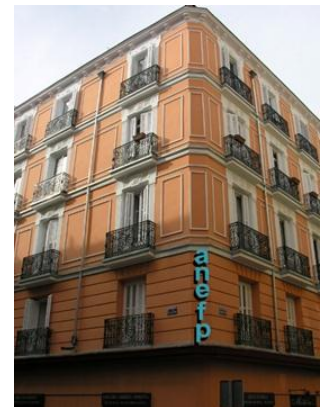
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Some data about anefp

anefp was set up in 1978 and represents the interests of self-care industry, including:

- **advertisable medicinal products (non-reimbursed non-subject to medical prescription)**
- **herbals medicines and products**
- **homeopathic medicines**
- **food supplements**
- **cosmetics**
- **non-reimbursed medical devices**



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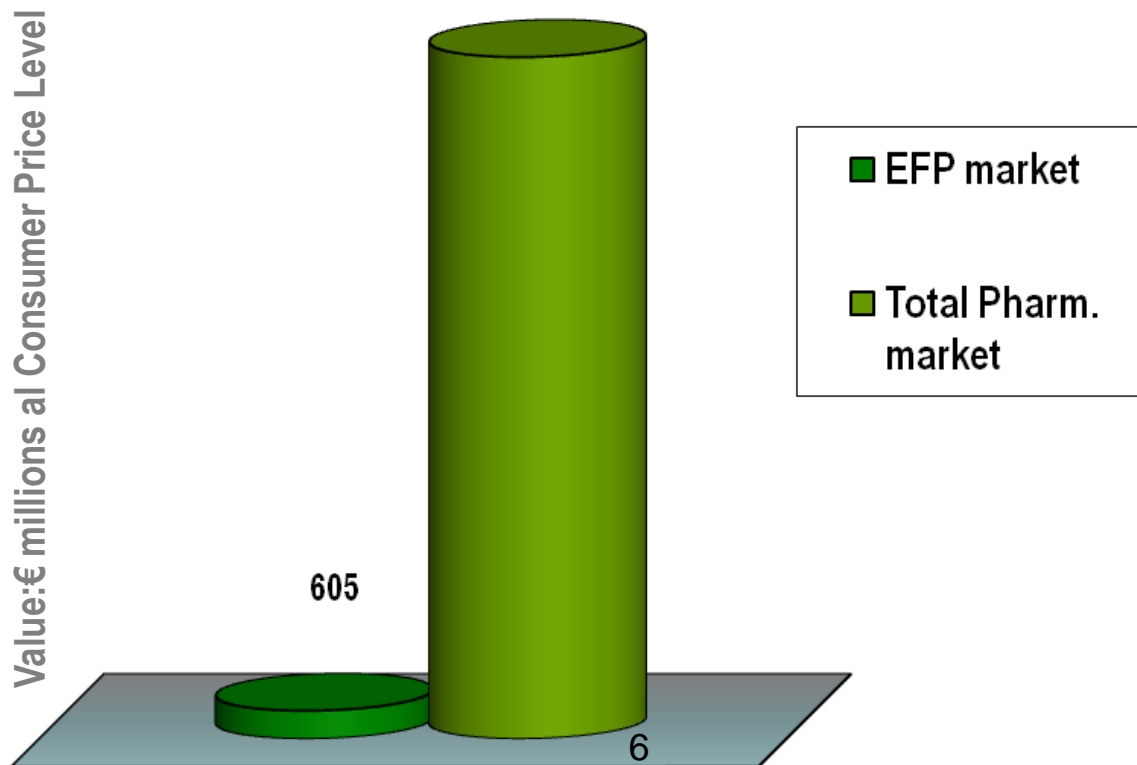
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Spanish EFP market 2008

The EFP market represents 4,14 % of the total pharmaceutical market (14,603 € millions).



Source: IMS

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Definition and characteristics of EFP medicines before new Medicines Law

(Law 29/2006, on 26 July 2006)

EFP *were* medicines:

- Intended for the relief, prevention and treatment of minor symptoms or syndromes to be used without medical supervision, and susceptible of self diagnosis by patients.
- The pricing freely set by the company.
- They could be advertised to the public.
- Their active ingredients had to be published in the positive list.

Current Spanish legislation on pharmaceuticals

The new legislation is a consequence of the Community Code transposition (Directives 2001/83/EC and 2004/27/EC)



Law 29/2006, of 26 July, on guarantees and rational use of medicinal products and medical devices



Royal Decree 1345/2007, of 11 October, on marketing authorisation, registration and dispensing conditions for medicines

Law 29/2006: key articles

Preamble IV: first time that the concept of “self-healthcare” and the importance of using non-prescription medicines are quoted in a piece of legislation.

Article 19: conditions for prescription and dispensing of medicines: only two kind of medicines are defined:

1. Prescription medicinal products
2. Non-prescription medicinal products

Law 29/2006: key articles

Article 19.4: *“The Spanish Agency for Medicinal Products may qualify as non-prescription medicines those intended for processes or conditions not requiring a precise diagnosis whose toxicological and clinical evaluation, use and route of administration data do not require medical prescription, such that these medicinal products may be used for self-healthcare and dispensed at a pharmacy by a pharmacist”.*

Law 29/2006: key articles

Article 78: set up the conditions for medicines to be advertised to the public.

Article 78.1: *“Medicinal products meeting all the requirements listed below, may be advertised to the general public:*

- Not financed by public funds
- Their composition and purpose are intended for use without intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary
- They are not psychotropic or narcotic substances

Definition of a non-prescription medicine
(Dir 2001/83/CE)

“The Ministry of Health will previously verify the fulfilment of those requirements to grant the authorisation”

Law 29/2006: key articles

Conclusion:

A medicinal product not subjected to a medical prescription can be advertised by the general public if it is not financed by public funds

Comparative characteristics of EFP medicines before/after New Medicines Law

Before

- **Positive list of ingredients**
- Self-diagnosis
- Advertisable to general public
- Non-prescription non-reimbursed medicines
- Freely set price

After

- Self-diagnosis (definition of non Rx medicine)
- Advertisable to general public
- Non-prescription non-reimbursed medicines
- Freely set price

Royal Decree 1345/2007 on marketing authorization, registration and dispensing conditions of medicines.

Aim: further develop Community Code on pharmaceuticals

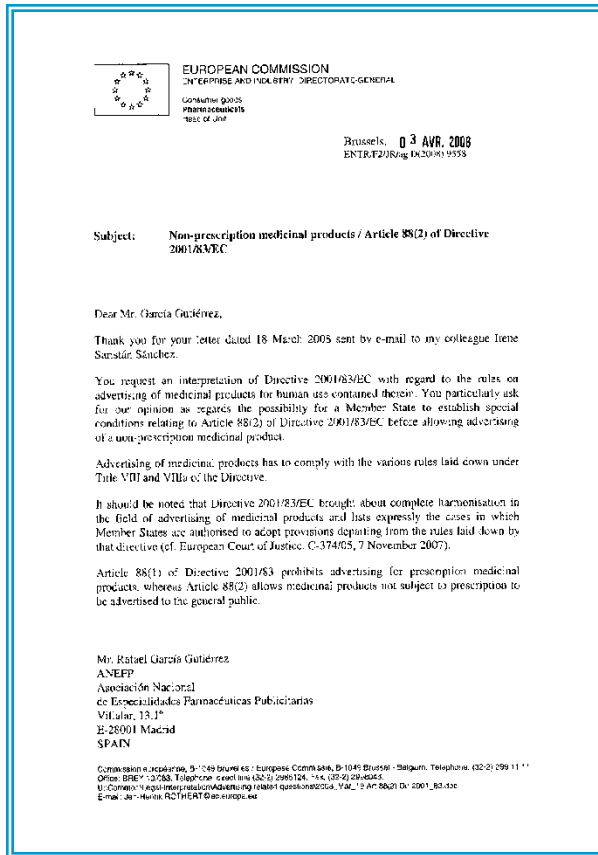
Key articles

Article 24: prescription and dispensing conditions of non-prescription medicines: includes definition of non-prescription medicines.

Article 25: “*Advertisable medicines*”, it compiles the conditions for a medicine to be advertised to the general public. AEMPS “*will verify (not will assess) these requirements by granting the preceptive authorisation*”.

Article 35: the name of a medicine will not lead to confusion with the name of any other medicine. *The wording of this article allows subjective interpretation, as no criteria were defined to identify confusion.*

18 March 2008: anep asked the European Commission whether national rules imposing further conditions on the advertising of non-prescription medicines were justified



EC reply: “Directive 2001/83/EC does not explicitly foresee the possibility for Member States to establish a set of rules allowing a further examination of a medicinal product, which already has been classified as a non prescription medicinal product, thus, eventually leading to a ban on advertising of this particular product.”

“When Article 88(2) of Directive 2001/83/EC refers to medicinal products which by virtue of their composition and purpose are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes (...), non-prescription medicinal products are meant. Once a medicinal product has been classified as such, no further analysis is possible.”

The letter confirms that European legislation invalidates any national requirements limiting the advertising of non-reimbursed non-prescription medicines anywhere in the European Union.

Conclusions

The new Spanish Pharmaceutical legislation has set up a clear legal framework on:

- Marketing authorisation procedures and proceedings
- Classification of medicines
- All non-prescription medicines which are non reimbursed can be advertised to the general public
- Positive list of active ingredients suitable for EFP suppressed



The Spanish market has the opportunity not to miss the train of Europe

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Some words on advertising of EFP medicines

Legislation currently in force:

- Article 78 Law 29/2006
- Some dispositions set up by the Community Code not yet implemented by the way of a national piece of legislation:
 - Remainder advertising: possibility to include only the invented name of the medicine (instead of the complete name of the medicinal product)
 - Some illnesses can now be mentioned in the ads (tuberculosis, cancer, chronic insomnia,...)
 - Possibility to mention that the medicinal product has been authorised by Health Authorities

Legislation to be abolished:

- Royal Decree 1416/1004, of 25 July, on advertising of medicinal products for human use

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Hopes for the future

(anefp wishes list)

Self-care Industry in Spain ask for the same rules as the rest of European countries.

Anefp recommendations to be included in the New Strategic plan of Pharmaceutical Policy of the MoH (not yet released):

- All non-Rx non-reimbursed medicines can be advertised to the general public
- Trend to harmonize OTC indications and compositions all around Europe
- MoH must apply established periods for marketing authorisation and variations procedures, avoiding unnecessary delays
- Authorisation of umbrella trade names in the same and in different legal status
- Authorisation of user friendly labelling for non-prescription medicines
- Not to apply additional restrictions to the advertising of non-prescription medicines, and speeding up the authorisation procedure (CPS)
- MoH will develop educational campaigns to promote self-care amongst citizens

And...

- **Anefp will continue its efforts in a bid for change. We believe on it.**

- **Paraphrasing Obama:**

Yes WE CAN!!!



THANK YOU VERY MUCH