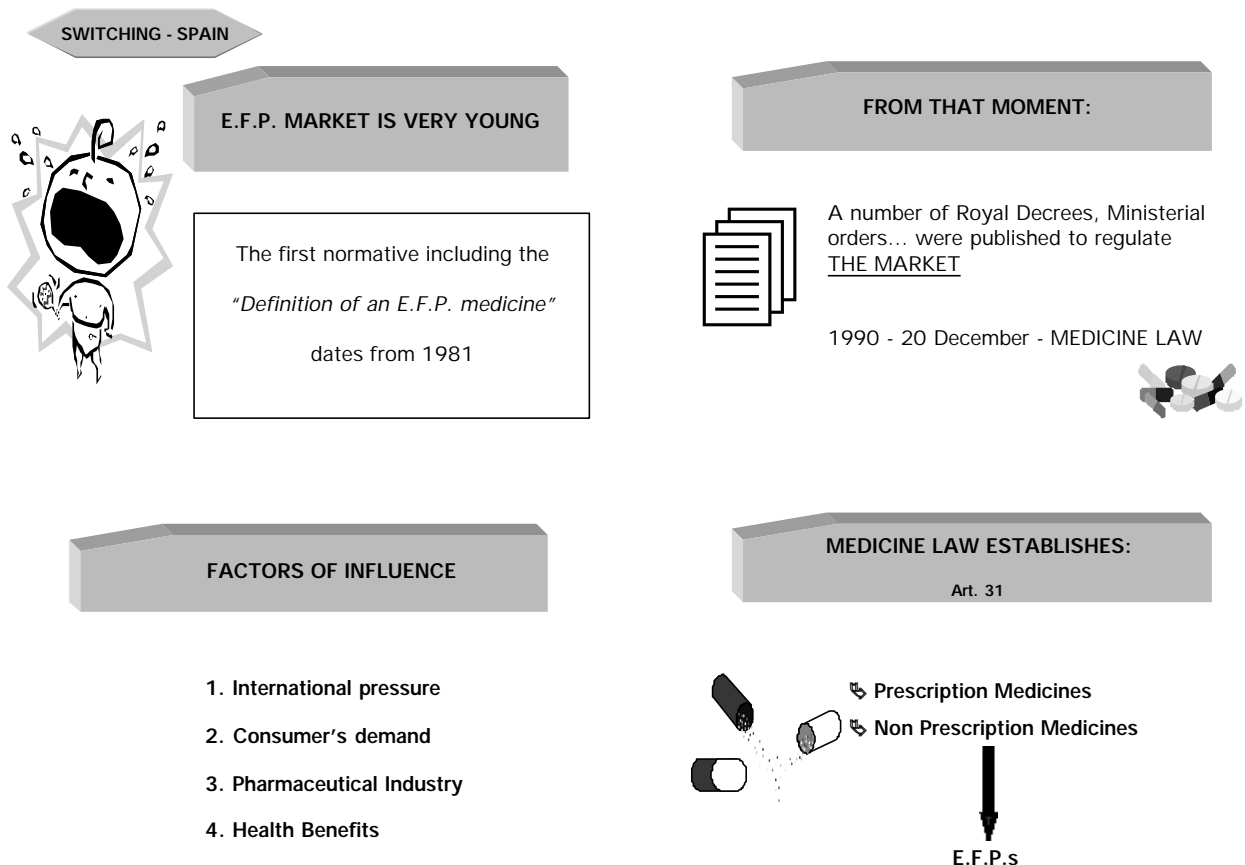


# WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

## Switching around the world: Spain

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### E.F.P's

- ✗ Intended for the prevention, relief or treatment of minor ailments.
- ✗ Composition: only active ingredients included in **the positive list**.
- ✗ No parenteral forms.
- ✗ Non reimbursed by S.S.
- ✗ Widely used
- ✗ Advertising in all media allowed.
- ✗ Only in pharmacy.

### CONDITIONS FOR THE APPROVAL

- 1 Intended for minor symptoms.
- 2 Wide Experience for the therapeutical indication applied and dosage.
- 3 Demonstration of the security and efficacy
- 4 International opinions (F.D.A.) and situation in the rest of E.U. members.

### SWITCHING

**A** - Active ingredient is not in the positive list and its inclusion must be approved.

**B** - Active ingredient is in the positive list → variation: Type II.

### THE POSITIVE LIST IS UPDATED EACH YEAR

Positive List

Applications from companies

Applications from ANEFP

*(negative lists; various companies interested in the same active ingredient at the same time, etc.)*

### A - ACTIVE INGREDIENT NOT INCLUDED

It is necessary to apply for its inclusion.

→ Experts Committee in the Ministry of Health. (ANEFP has representation).

### IMPORTANT ACTIVE INGREDIENTS APPROVED DURING LAST YEARS

- ✗ LOPERAMIDE
- ✗ CIMETIDINE
- ✗ FAMOTIDINE
- ✗ RANITIDINE
- ✗ IBUPROFEN
- ✗ MINOXIDIL (topical)
- ✗ NICOTINE (gum and patches)
- ✗ NAPROXEN
- ✗ PIROXICAM (topical)
- ✗ HYDROCORTISONE (topical and mouth problems)
- ✗ ACETYLCYSTEINE (mucolytic)
- ✗ CROMOGLYCIC ACID (nasal, and ophthalmological).

### EXPERTS COMMITTEE

- ☞ General Subdirection of Medicines Evaluation.
- ☞ General Subdirection of Medicines Control (Pharmacovigilance).
- ☞ General Subdirection of Pharmaceutical Planification (Medicines Information centre - CINIME).
- ☞ National Centre of Pharmacobiology.
- ☞ General Subdirection of Medical Devices.
- ☞ Pharmaceutical Industry - ANEFP.

### B - ACTIVE INGREDIENT IS WITHIN THE POSITIVE LIST.


VARIATION TYPE II.


📄 SPC, 📄 LeafLet and 🧴 pack must fulfill


with EFP conditions,

(Medicine law, Royal Decree 2236/1993 - December 17 on the labelling and on package leaflets.

**PROBLEMS**

 **TRADE NAMES - UMBRELLA BRANDS**  
"An E.F.P. cannot have the same name as another medicine with a different Legal Status"

 **THERAPEUTICAL INDICATIONS:**  
Progress to be made with regard to those indications where self-recognition is involved

 **MUTUAL RECOGNITION:** legal status not included.

**FUTURE**



**A.E.M. - E.F.P. Department**

A.N.E.F.P. succeeded in the creation of an E.F.P. department in the A.E.M. where all applications (new registrations, variations etc., will be studied independently of other medicines (Rx, Generics, etc.)

