

# Patient Support Programs and Market Research Programs in Pharmacies: Managing Safety Information

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## Disclosure

- The author is employed by the National Association of Pharmacies (ANF) and is Executive Director of CEFAR (Centre for Health Evaluation & Research).
- ANF supports pharmacy owners in the implementation of various Patient Programs
- ANF is member of PGEU (Pharmaceutical Group of European Union)
- CEFAR performs several research studies on Pharmacoepidemiology, Health Economics & Outcomes Research, Pharmaceutical Market Research **through the network of pharmacies**, the majority of which are financed by ANF, and some by the pharmaceutical industry.
- CEFAR is a member of the **ISPE** (International Society for Pharmacoepidemiology) and of **ENCePP** (European Network of Centres for Pharmacoepidemiology & Pharmacovigilance) of EMA

# What we know at the time of authorization



# What we don't know...



**What happens when the medicine  
is used in normal practice**

**What is its full benefit / risk profile?**

# Gap between information at MA and post-MA

- **At Marketing Authorization:**
  - Ideal patients
  - Efficacy
  - Safety data (most frequent, captured in short time horizon of RCT)
- **Real-World:**
  - All kinds of patients
  - Off-label use (intended and not intended)
  - Adherence/Persistence  $\Rightarrow$  Effectiveness
  - Safety (less frequent, delayed AE, AE in patients not in RCT)
  - Need to capture all opportunities of patient interaction to improve systematic data collection to  $\uparrow$  PATIENT SAFETY
  - Patient's natural regular interaction... **Pharmacy**

## GVP Module VI


### VI.C.2.2.11. Reports from PSPs and MRPs

#### Patient Support Programs (PSPs):

«A PSP is an **organised system** where a MAH receives and collects information relating to the **use** of its medicinal products. Examples are **post-authorisation patient support and disease management programmes, surveys** of patients and healthcare providers, information gathering on **patient compliance**, or **compensation/ reimbursement schemes**»

#### Market Research Program (MRP):

«A MRP refers to the systematic collection, recording and analysis by a MAH of data and findings about its medicinal products, relevant for marketing and business development»



«**Safety reports** originating from those programmes should be considered as **solicited reports**»

# Pharmacy

- **Dispensing software with Patient records (refill data only):**
  - Adherence + Persistence No safety data
  - Patient Access Programs (Reimbursed by MAH) May capture safety data
- **When adding questionnaire + Pharmacist (qualified provider):**
  - Spontaneous reporting Designed to capture safety data
  - Managed Entry Programs, as per RMP Designed to capture safety data (Post-authorization Study)
  - Observational Studies
  - Patient Compliance Programs
  - Market Research StudiesNot designed to capture safety data.  
But unintended safety data **may be** collected



**Huge potential Real-World Data, incl. safety data,  
for MAH + Regulators**

# **SPONTANEOUS REPORTING**

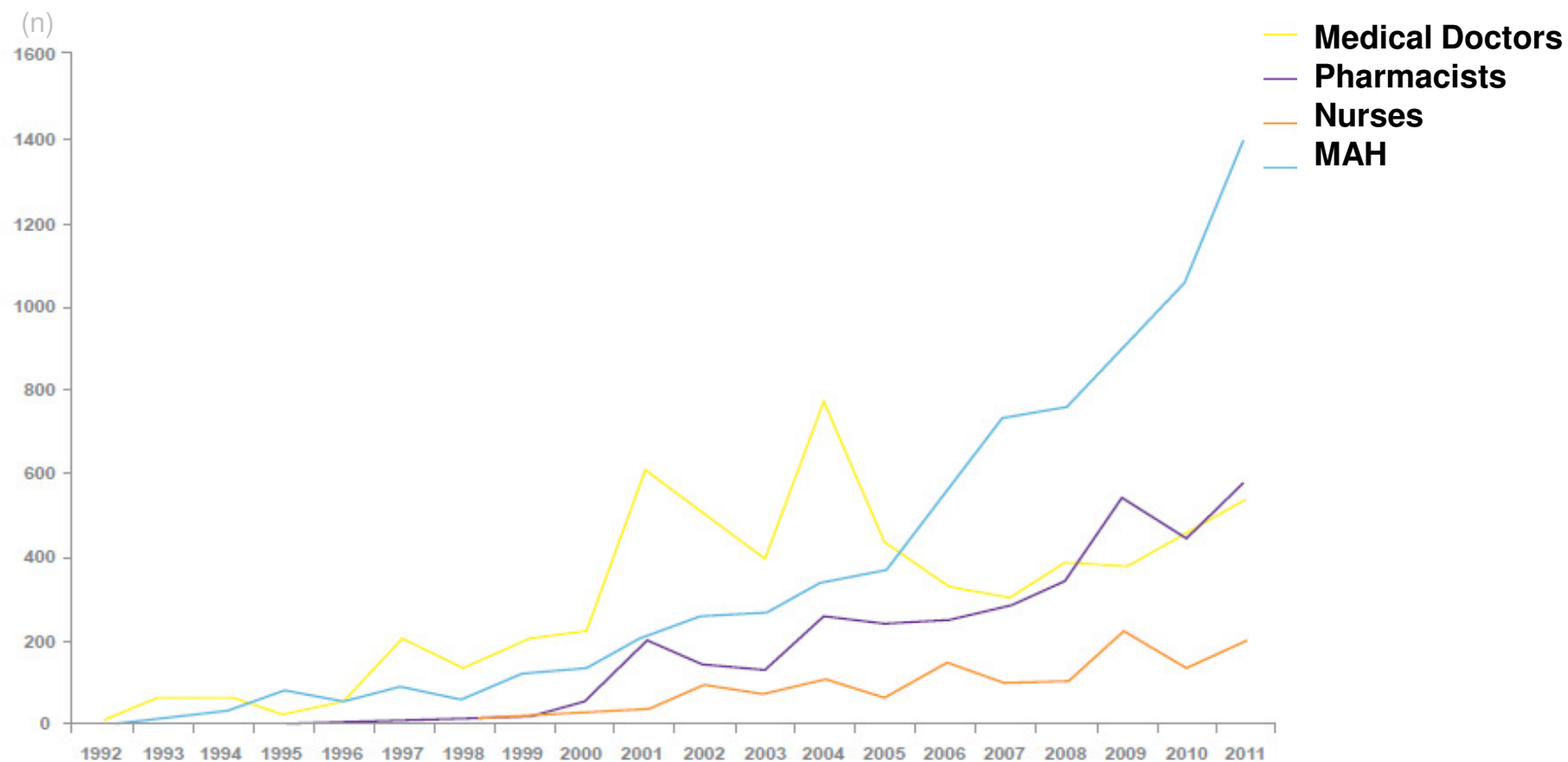
## **“Professional duty”**

### **of Community Pharmacists**

### **within the Pharmacovigilance System**



# Spontaneous Reporting in Portugal

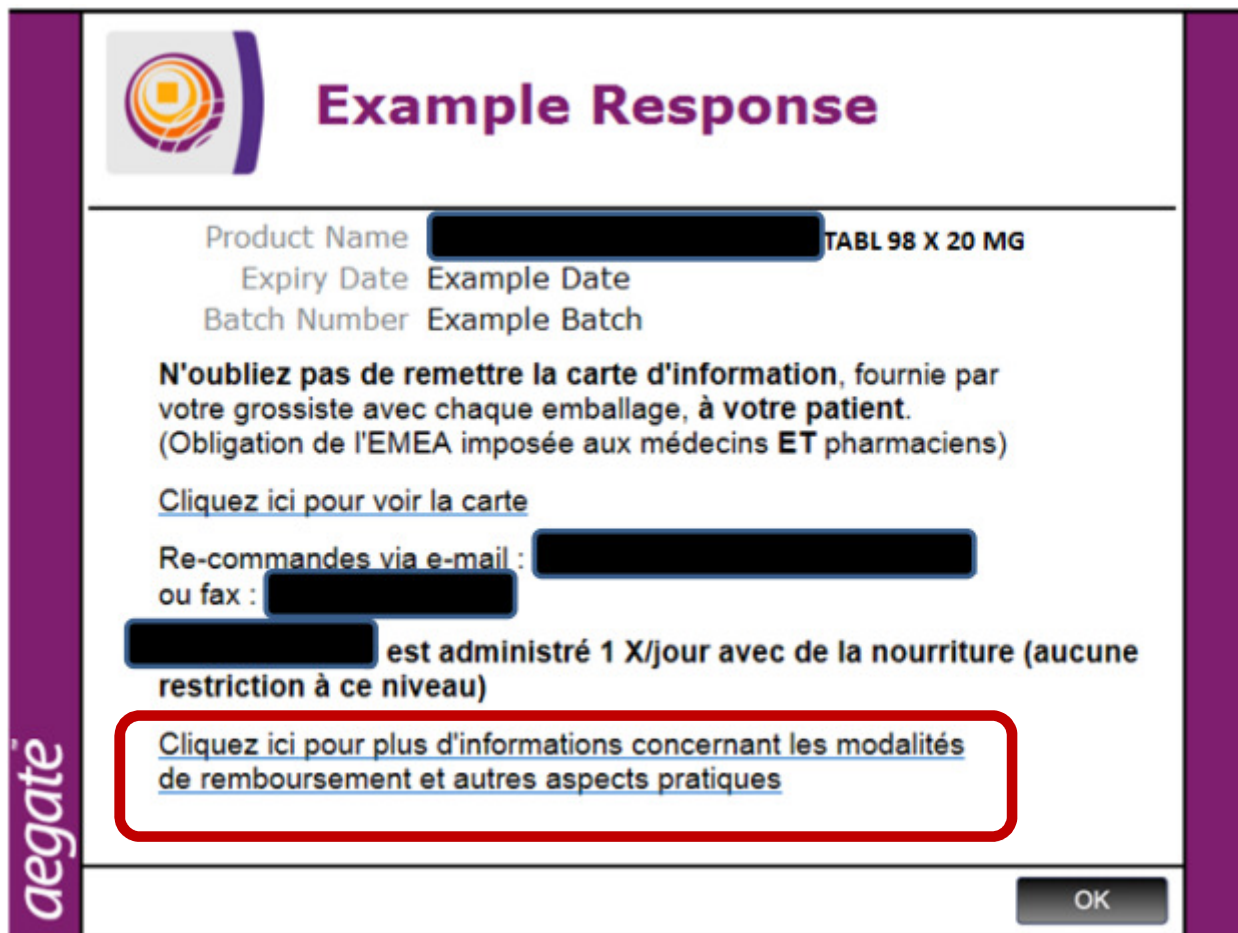


## **SOLICITED REPORTING**

### **Examples of Programs that make use of the Network of Pharmacies and of Community Pharmacists**

**CANNOT be regarded as “professional duty”  
of Community Pharmacists  
but may be commissioned by MAH**

## Patient Access Programs (Belgium)



**Example Response**

Product Name [REDACTED] TABL 98 X 20 MG  
 Expiry Date Example Date  
 Batch Number Example Batch

**N'oubliez pas de remettre la carte d'information**, fournie par votre grossiste avec chaque emballage, à votre patient.  
 (Obligation de l'EMA imposée aux médecins **ET** pharmaciens)

[Cliquez ici pour voir la carte](#)

Re-commandes via e-mail : [REDACTED]  
 ou fax : [REDACTED]

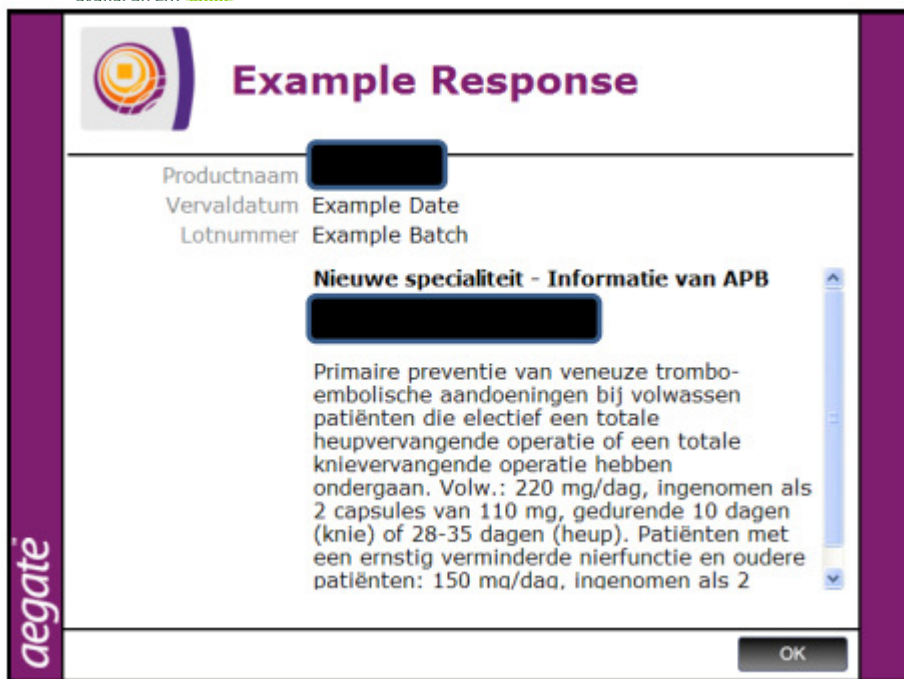
[REDACTED] est administré 1 X/jour avec de la nourriture (aucune restriction à ce niveau)

[Cliquez ici pour plus d'informations concernant les modalités de remboursement et autres aspects pratiques](#)

OK

Automated flag alert in dispensing software: when medicine pack is scanned:

## Managed Entry Programs, as per RMP (Belgium)



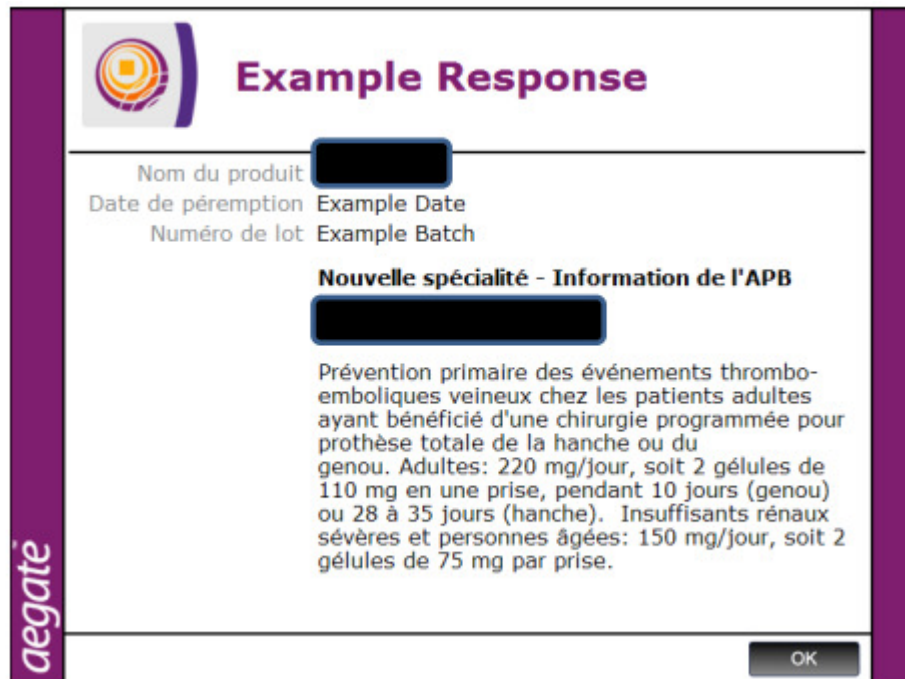
**Example Response**

Productnaam [Redacted]  
 Vervaldatum Example Date  
 Lotnummer Example Batch

**Nieuwe specialiteit - Informatie van APB**  
 [Redacted]

Primaire preventie van veneuze trombo-embolische aandoeningen bij volwassen patiënten die electief een totale heupvervangende operatie of een totale knievervangende operatie hebben ondergaan. Volw.: 220 mg/dag, ingenomen als 2 capsules van 110 mg, gedurende 10 dagen (knie) of 28-35 dagen (heup). Patiënten met een ernstig verminderde nierfunctie en oudere patiënten: 150 mg/daa, ingenomen als 2

OK



**Example Response**

Nom du produit [Redacted]  
 Date de péremption Example Date  
 Numéro de lot Example Batch

**Nouvelle spécialité - Information de l'APB**  
 [Redacted]

Prévention primaire des événements thrombo-emboliques veineux chez les patients adultes ayant bénéficié d'une chirurgie programmée pour prothèse totale de la hanche ou du genou. Adultes: 220 mg/jour, soit 2 gélules de 110 mg en une prise, pendant 10 jours (genou) ou 28 à 35 jours (hanche). Insuffisants rénaux sévères et personnes âgées: 150 mg/jour, soit 2 gélules de 75 mg par prise.

OK

Automated flag alert in dispensing software: when medicine pack is scanned

**New medicine on the market (under additional monitoring – inverted black triangle)**

**Message live from day 1 of commercialisation up till 2 months after product launch**



## Managed Entry Programs, as per RMP (The Netherlands)

**Case 1:** Pharmacy dispensing software has an extensive medication surveillance, based on the extensive KNMP medicines database.

Ex: Pregnancy prevention module for users of **Isotretinoin**

**Case 2:** Pharmacies, can act as an inclusion point for real-world data collection programs (**e.g. web intensive monitoring programs**)

# Pattern of Use of HPV Vaccine and Adherence to Vaccination Schedule Among Individuals Excluded From The Portuguese Immunization Program

## HPV Vaccine Adverse Events Following Immunization recorded in Pharmacies

**One third of study participants (63 out of 209) reported at least one AE**

Adverse Event Following Immunization	1st Dose n (%)	2nd Dose n (%)	3rd Dose n (%)	Total n (%)
<b>Local Injection Site Reactions</b> (pain, swelling, bruising, redness, itching/pruritus)	29 (63.04)	29 (72.50)	32 (78.05)	<b>90 (70.87)</b>
Fever	3 (6.52)	0 (0.00)	0 (0.00)	3 (2.36)
Headache, Dizziness	4 (8.70)	4 (10.00)	3 (7.32)	11 (8.66)
Gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain)	3 (6.52)	0 (0.00)	1 (2.44)	4 (3.15)
Others	7 (15.22)	7 (17.50)	5 (12.20)	19 (14.96)
<b>Total</b>	<b>46 (100.00)</b>	<b>40 (100.00)</b>	<b>41 (100.00)</b>	<b>127 (100.00)</b>

# Adherence and Persistence in Pharmacies (PORTUGAL)

**ESTUDO**  
**“ADESÃO E PERSISTÊNCIA À**  
**TERAPÊUTICA COM**  
**BIFOSFONATOS NO**  
**TRATAMENTO DA**  
**OSTEOPOROSE PÓS-**  
**MENOPÁUSICA”**

**DESCRIPTIVO**

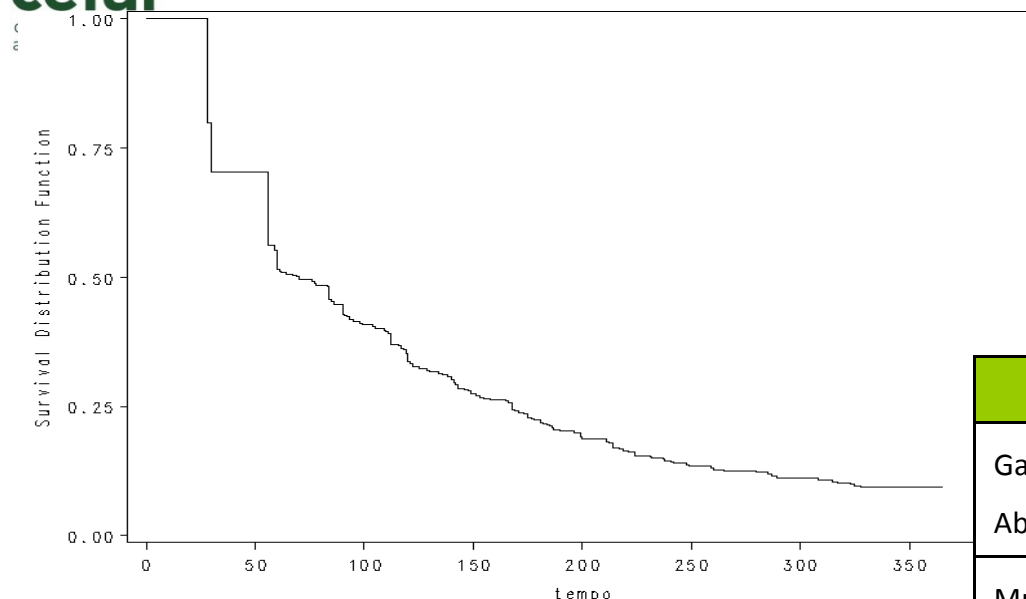


**Initiated in 2011**

**1st Database Observational Study  
in Community Pharmacies  
Patient cohort under observation  
for 24 months**



# Persistence with Oral Bisphosphonate Treatment for Postmenopausal Osteoporosis in Portugal

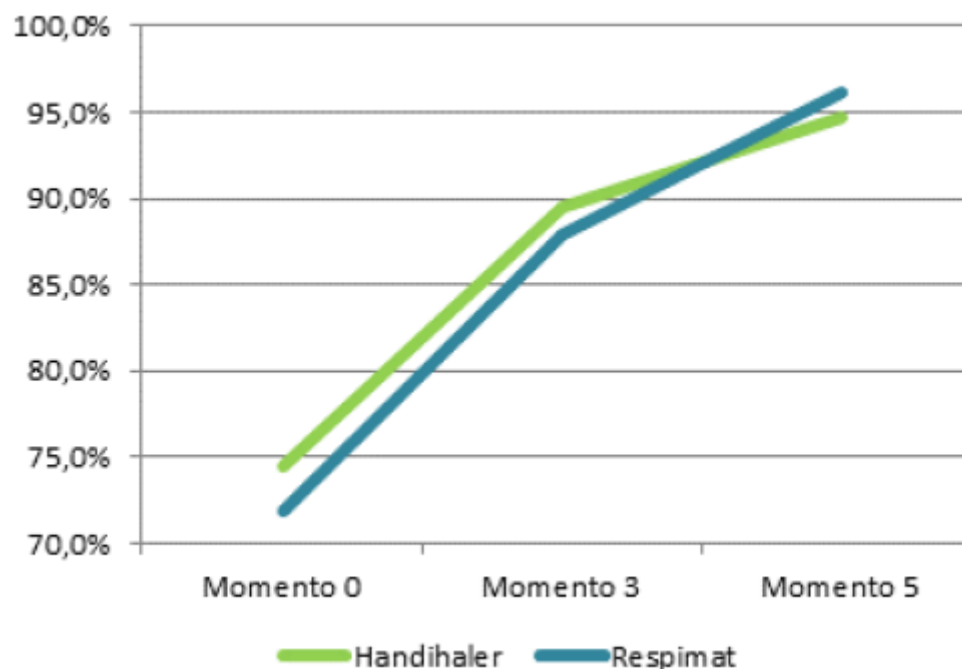


At 12 months of follow-up, 50 out of 427 recruited patients reported that treatment interruption was due to an **adverse event**.

Adverse events	n (%)*
Gastrointestinal disorders (e.g., Nausea, Diarrhea, Abdominal pain)	36 (72.0%)
Musculoskeletal and connective tissue disorders (e.g., Musculoskeletal pain, joint swelling/joint pain)	17 (34.0%)
Nervous system disorders (e.g., headache)	11 (22.0%)
Tiredness / general uncomfortable feeling	6 (12.0%)
Heartburn	6 (12.0%)
Others	4 (8.0%)
<b>Total</b>	<b>50 (100.0%)</b>



# Pharmacy-Based Intervention in COPD patients

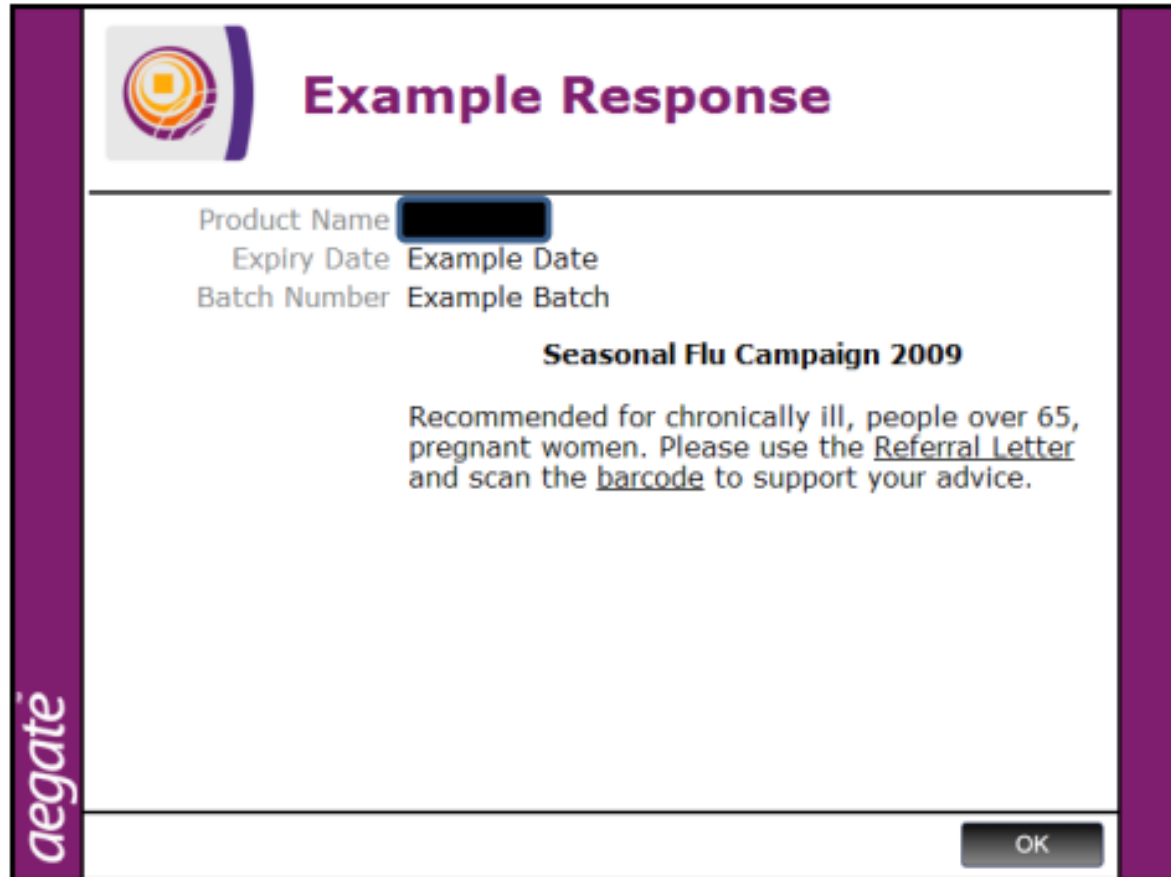


The intervention led by the Pharmacists resulted in the improvement of inhalation technique for both Spiriva® devices. The scores reached at 5 months were  $\geq 95\%$  and may represent the achievement of the correct performance following a structured intervention in Pharmacies.

GRUPO 

Torre C, Guerreiro JP, Madeira A, Lopes F, Mendes Z, Miranda A, Santos C, Costa S. *Pharmacy-Based Intervention in COPD patients – Portuguese Pharmacists can effectively improve inhalation technique!*. International Pharmaceutical Federation (FIP) Congress, Dublin, September, 2013.

## Public Health Protection (Belgium)



The dialog box has a purple border. On the left side, the word 'aegate' is written vertically. At the top left is a circular logo with orange and purple segments. The title 'Example Response' is in purple. Below it, there are three lines of text: 'Product Name' followed by a blacked-out box, 'Expiry Date Example Date', and 'Batch Number Example Batch'. The main text is 'Seasonal Flu Campaign 2009' followed by a paragraph: 'Recommended for chronically ill, people over 65, pregnant women. Please use the Referral Letter and scan the barcode to support your advice.' At the bottom right is an 'OK' button.

**Example Response**

Product Name [REDACTED]  
Expiry Date Example Date  
Batch Number Example Batch

**Seasonal Flu Campaign 2009**

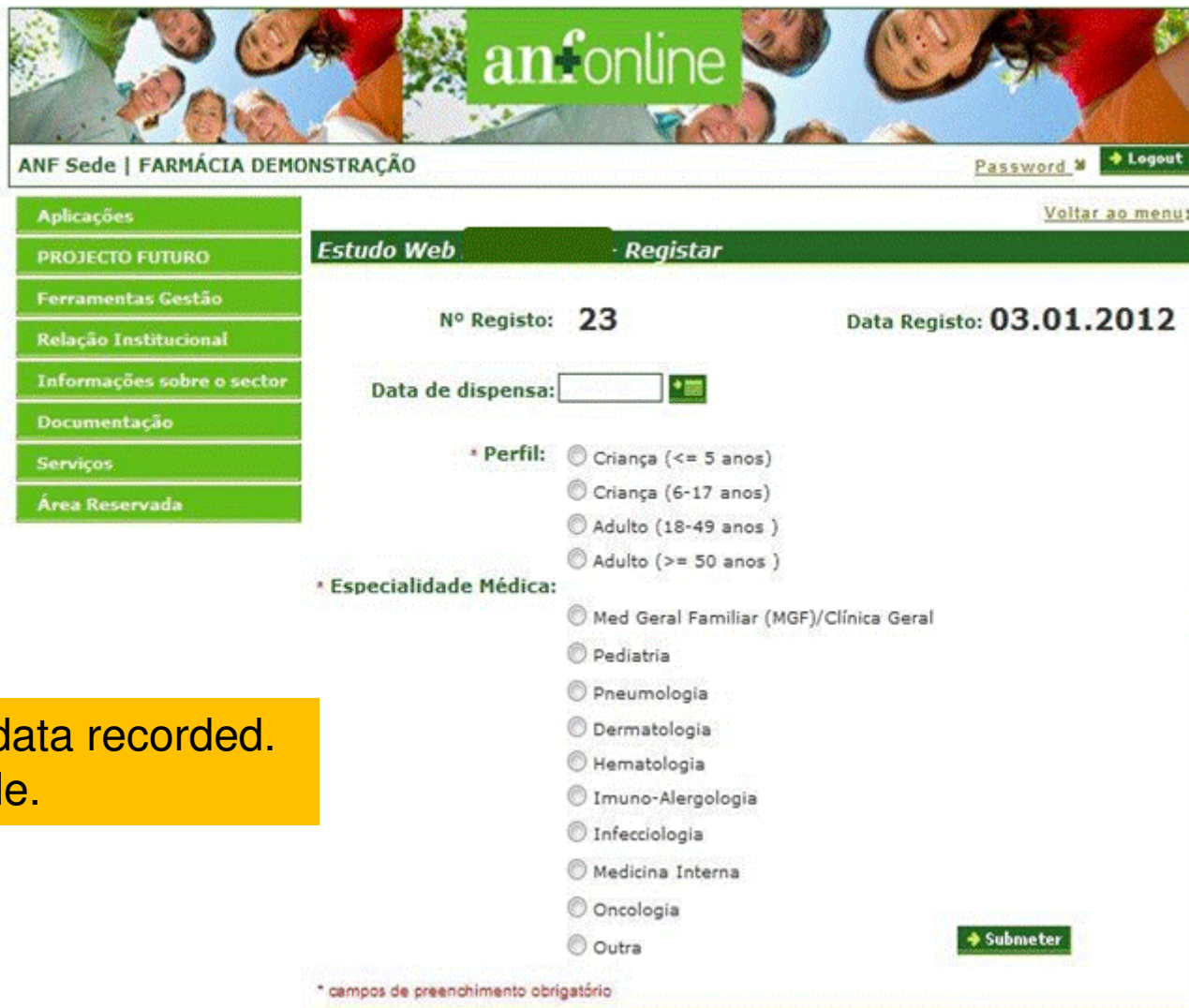
Recommended for chronically ill, people over 65,  
pregnant women. Please use the Referral Letter  
and scan the barcode to support your advice.

aegate

OK

Pop-up about **flu vaccination** when dispensing medicines  
to at-risk population: referral

# Web Market Research Program in the Pharmacy (PORTUGAL)



ANF Sede | FARMÁCIA DEMONSTRAÇÃO

anfonline

Logout

Voltar ao menu

Estudo Web · Registrar

Nº Registo: 23 Data Registo: 03.01.2012

Data de dispensa:

\* Perfil:

- ☐ Criança (<= 5 anos)
- ☐ Criança (6-17 anos)
- ☐ Adulto (18-49 anos)
- ☐ Adulto (>= 50 anos)

\* Especialidade Médica:

- ☐ Med Geral Familiar (MGF)/Clínica Geral
- ☐ Pediatria
- ☐ Pneumologia
- ☐ Dermatologia
- ☐ Hematologia
- ☐ Imuno-Alergologia
- ☐ Infecçiology
- ☐ Medicina Interna
- ☐ Oncologia
- ☐ Outra

Submeter

\* campos de preenchimento obrigatório

No safety data recorded.  
But possible.

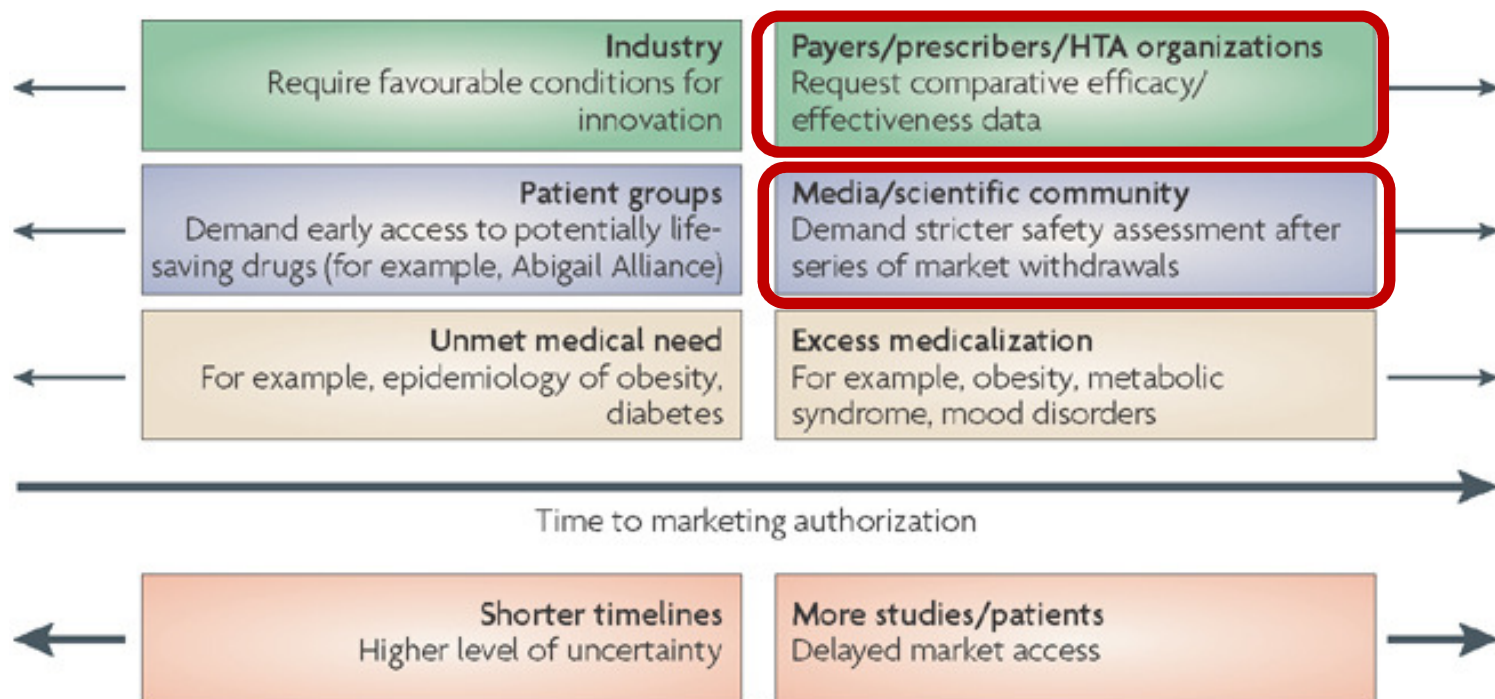


# Future opportunities for safety management through the network of Pharmacies

## PHARMACY-BASED:

- **Disease Management Programs**
- **Medication Therapy Management**
- **Patient Compliance Programs**
- **Pharmacy-based Immunization Programs**
- **Patient Reporting Outcomes (Safety Event Reporting) – CEFAR suggested to include this possibility in the Draft Guide of PROSPER Consortium**

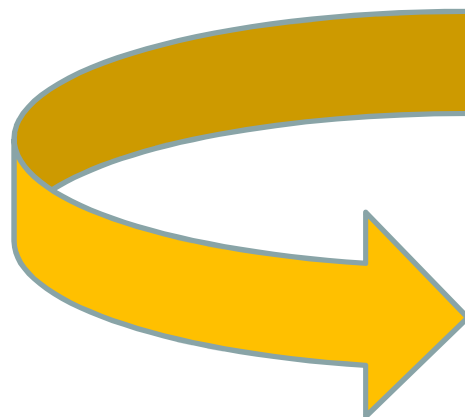
# Real-World Data will be more important



Nature Reviews | Drug Discovery

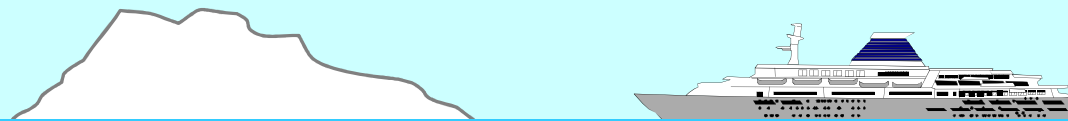
# New Pharmacovigilance Legislation

**Safety**



**Benefit / Risk  
assessment through  
the entire lifecycle of  
the Medicine**

# What we know at the time of authorization



Source: Thomas Lönngren, 20 August 2010

# What we don't know...



**What happens when the medicine  
is used in normal practice**

**What is its full benefit / risk profile?**



# Pharmacies - an Inclusion Point for Real-World Data Collection Programmes.

## Bridging the gap between RCT and Real-World – A call to Arms to the Community Pharmacies



1. **New Phv legislation (July 2012): Strengthening post-authorisation of medicines** (lifecycle benefit-risk management).
  - Risk Management Plans
  - Post-authorization safety studies (PASS) AND post-authorization efficacy studies (PAES)
  - Medicinal products under additional monitoring
2. **EU conditional marketing authorization (CMA)**

# Thank You

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