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

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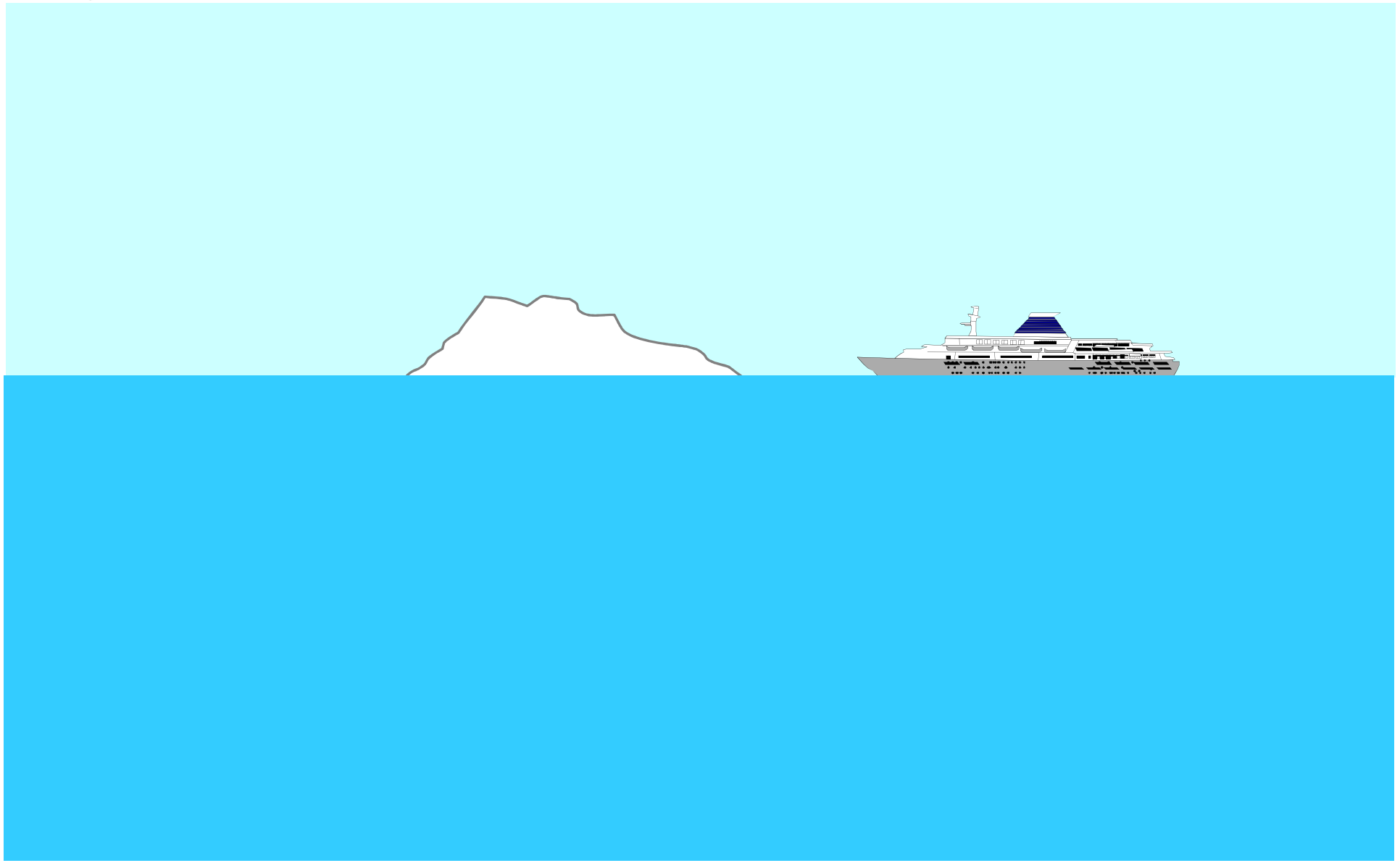
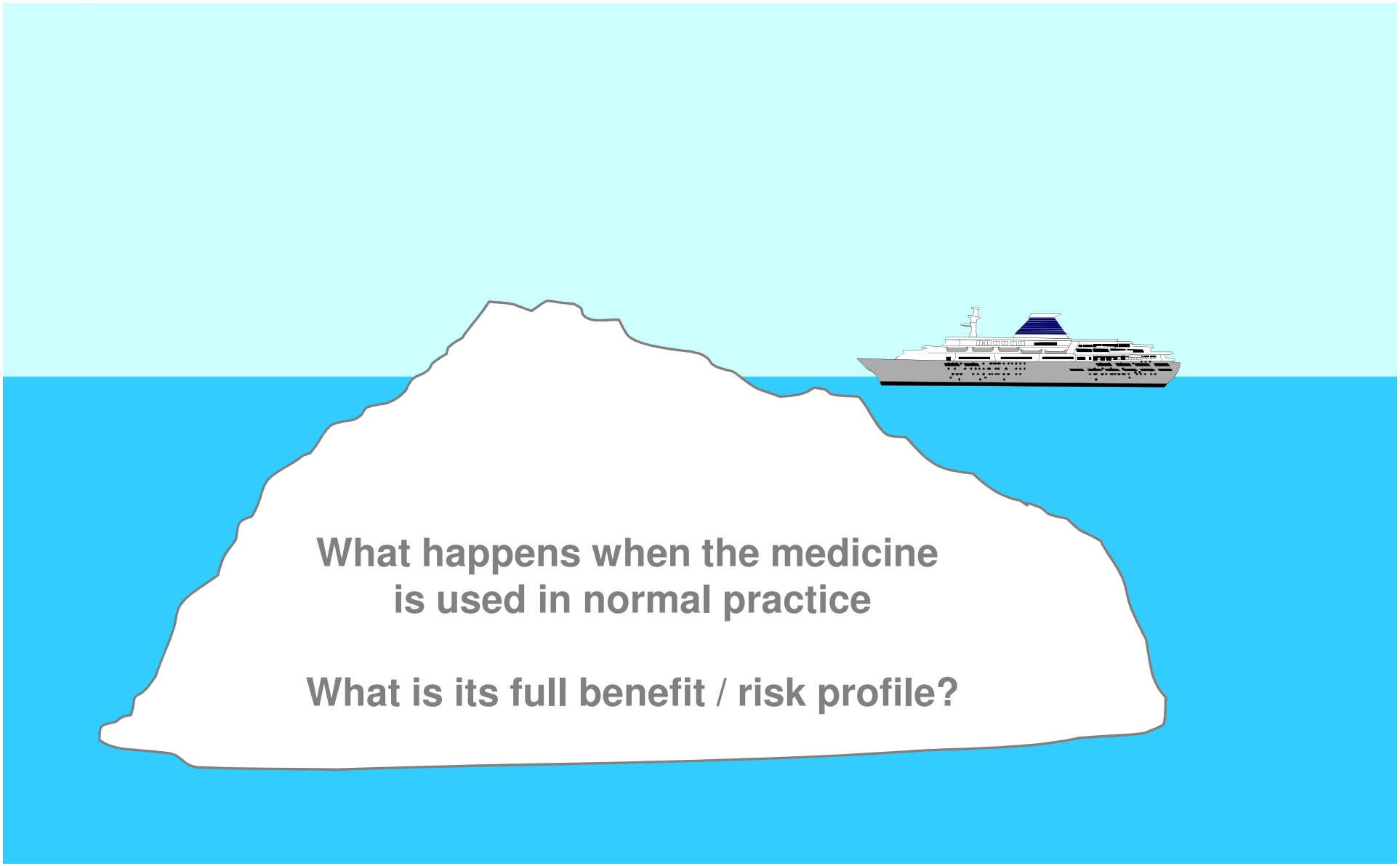
Disclosure

- 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…



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 ⇒ Effectiveness
  - Safety (less frequent, delayed AE, AE in patients not in RCT)
  - Need to capture <u>all</u> opportunities of patient interaction to improve systematic data collection to ↑ PATIENT SAFETY
  - Patient's <u>natural</u> 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

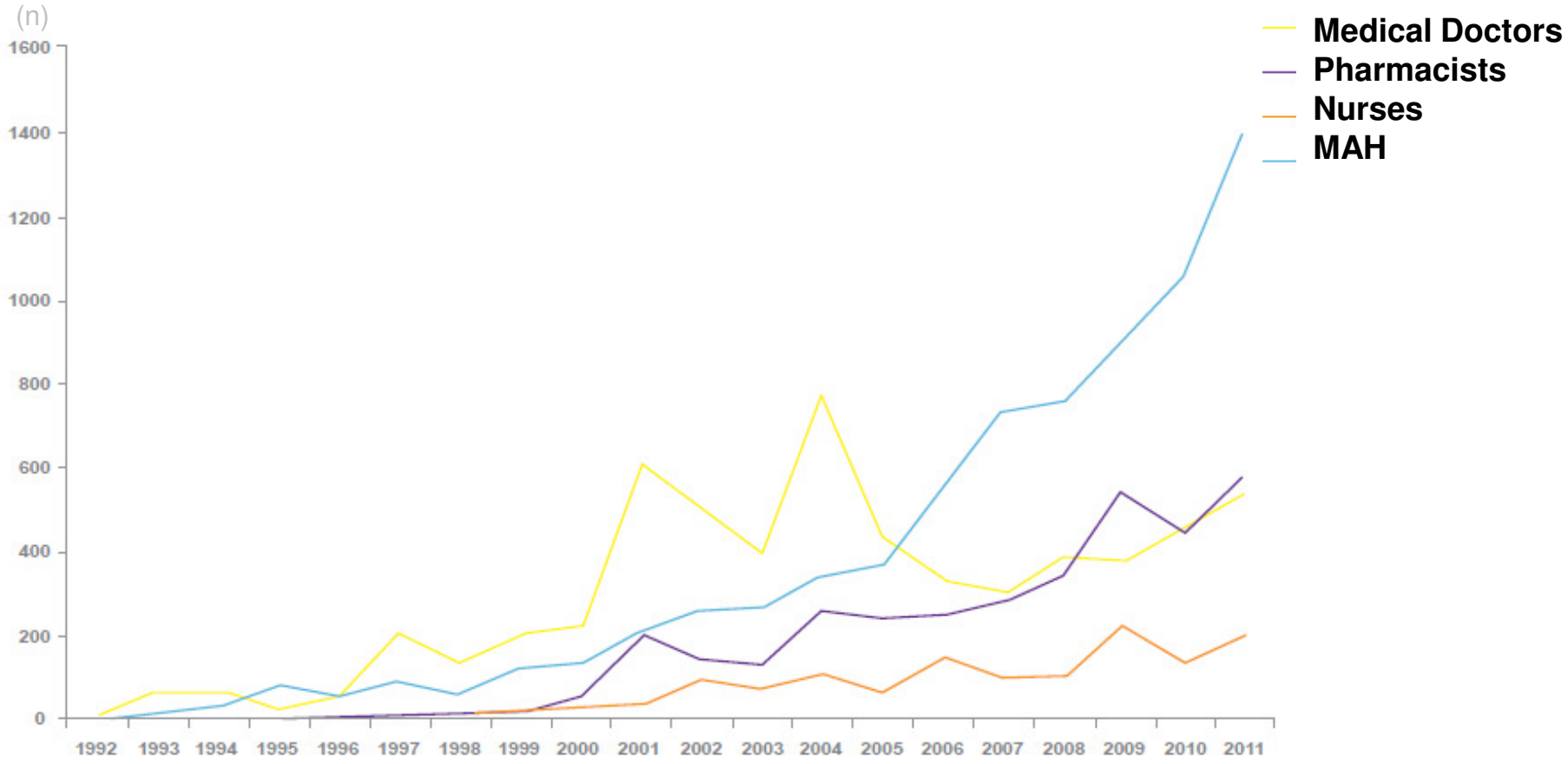
- **Dispensing software with Patient records (refill data only):**
  - Adherence + Persistence — No safety data
  - Patient Access Programs (Reimbursed by MAH) — May capture safety data
- **When adding questionnaire + Pharmacist (qualified provider):**
  - Spontaneous reporting — Designed to capture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

  Not 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



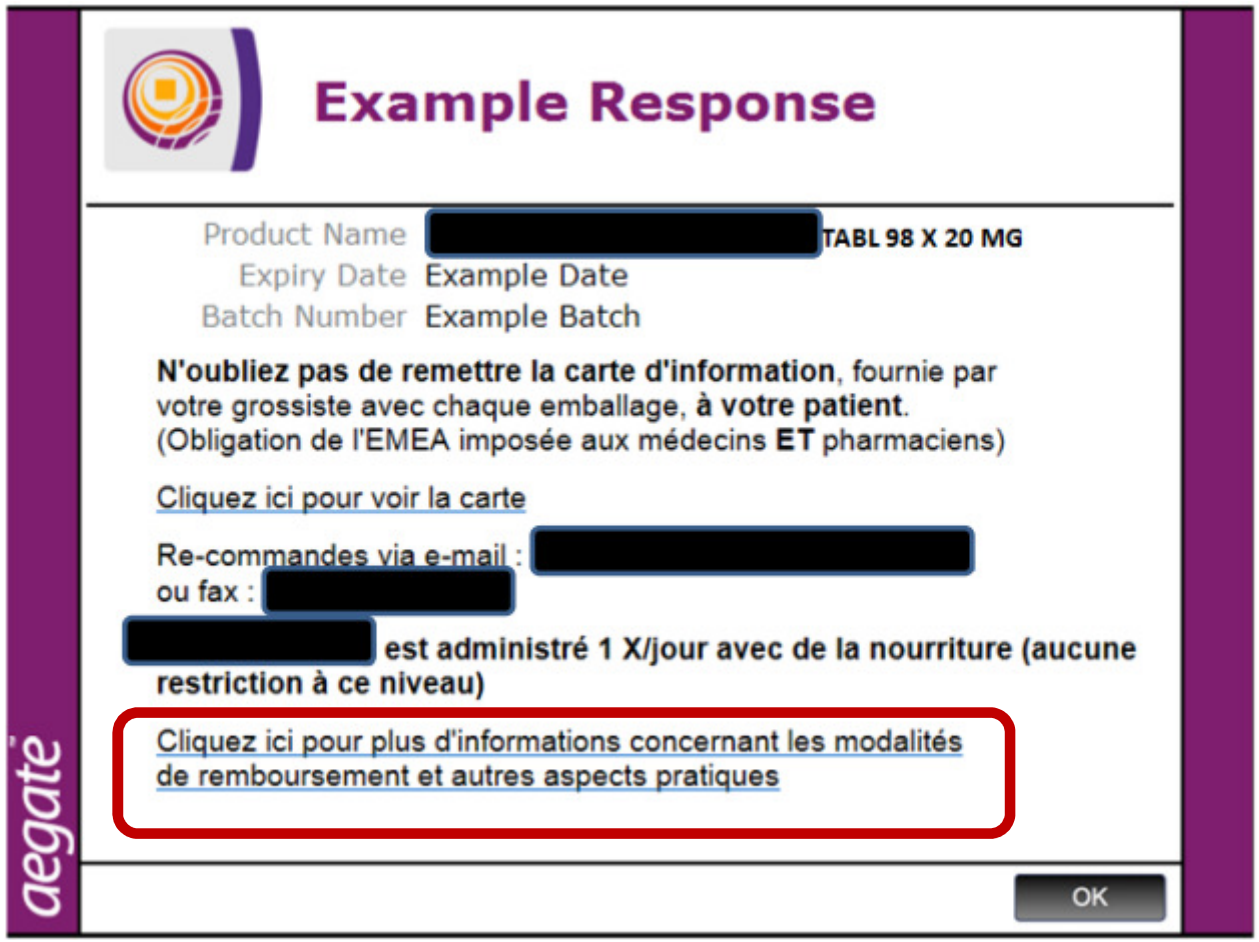
Herdeiro MT *et al.* The Portuguese Pharmacovigilance System. Acta Med Port. 2012 Jul-Aug;25(4):241-9.

SOLICITED REPORTING

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

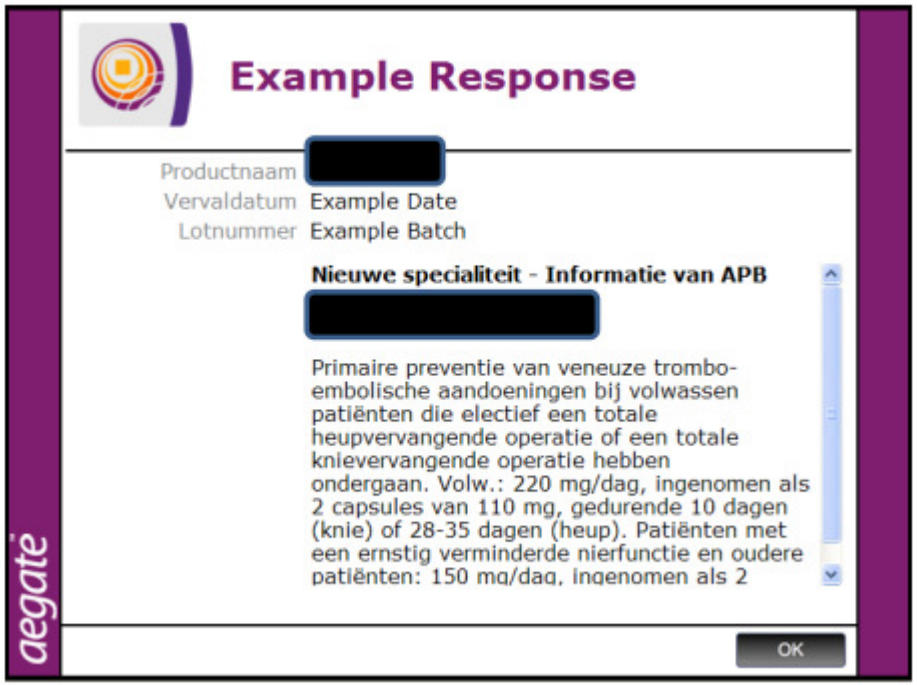
CANNOT be regarded as "professional duty" of Community Pharmacists but may be commissioned by MAH

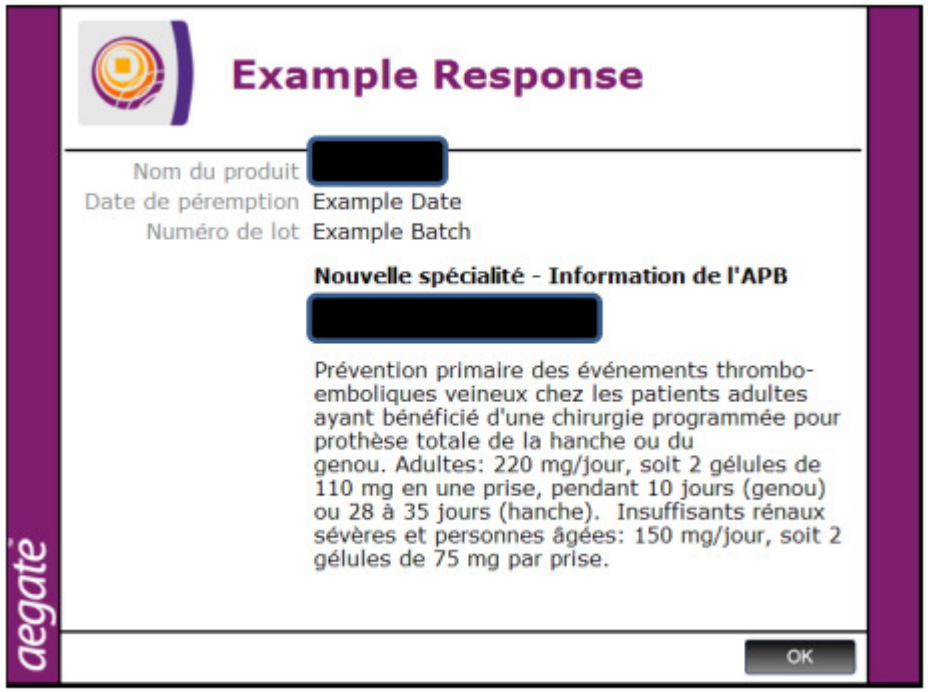
Patient Access Programs (Belgium)



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

Managed Entry Programs, as per RMP (Belgium)





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 Immnunization	1st Dose n (%)	2nd Dose n (%)	3rd Dose n (%)	Total n (%)
Local Injection Site Reactions (pain, swelling, bruising, redness, itching/pruritus)	29 (63.04)	29 (72.50)	32 (78.05)	**90 (70.87)**
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)
Total	46 (100.00)	40 (100.00)	41 (100.00)	127 (100.00)

Financed by Sanofi Pasteur MSD

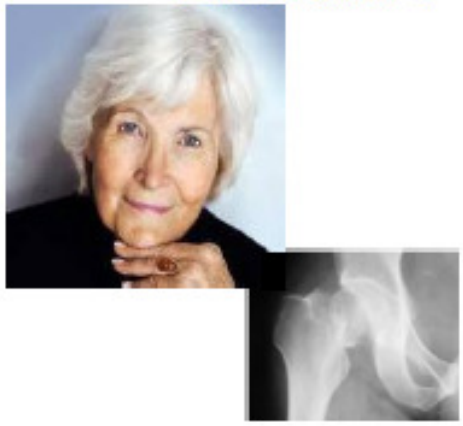
Torre C, Guerreiro J, Mendes Z, Costa S, Miranda A. Padrão de Utilização da Vacina Contra o HPV. Oral communication presented in 19th Portuguese Congress for Obstetrics and Gynaechology 2011, 16 to 19 March, Porto. Acta Obstétrica e Ginecológica Portuguesa 2011 Suppl 1, p. 35

Adherence and Persistence in Pharmacies (PORTUGAL)

ESTUDO

"ADESÃO E PERSISTÊNCIA À TERAPÊUTICA COM BIFOSFONATOS NO TRATAMENTO DA OSTEOPOROSE PÓS-MENOPÁUSICA"

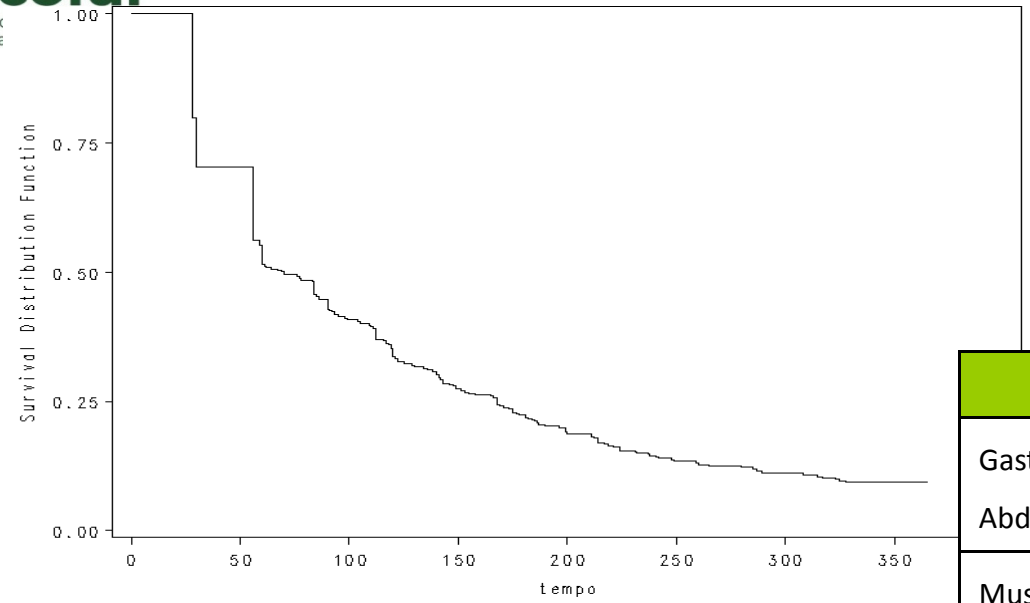
DESCRITIVO



Initiated in 2011

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

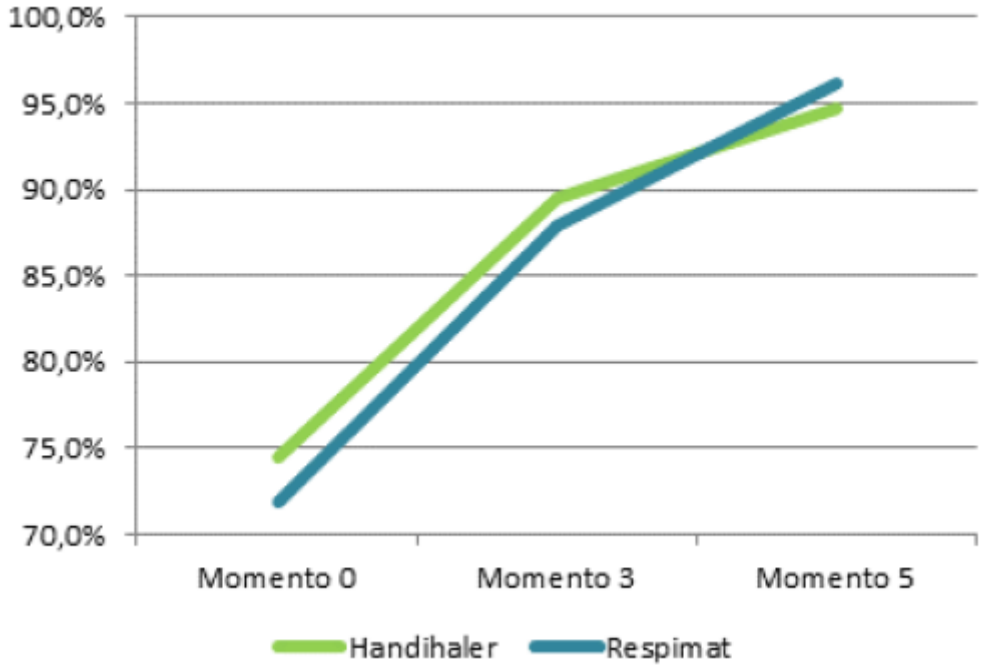
Persistence with Oral Bisphosphonate Treatment for Postmenopausal Osteoporosis in Portugal



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%)
Total	50 (100.0%)

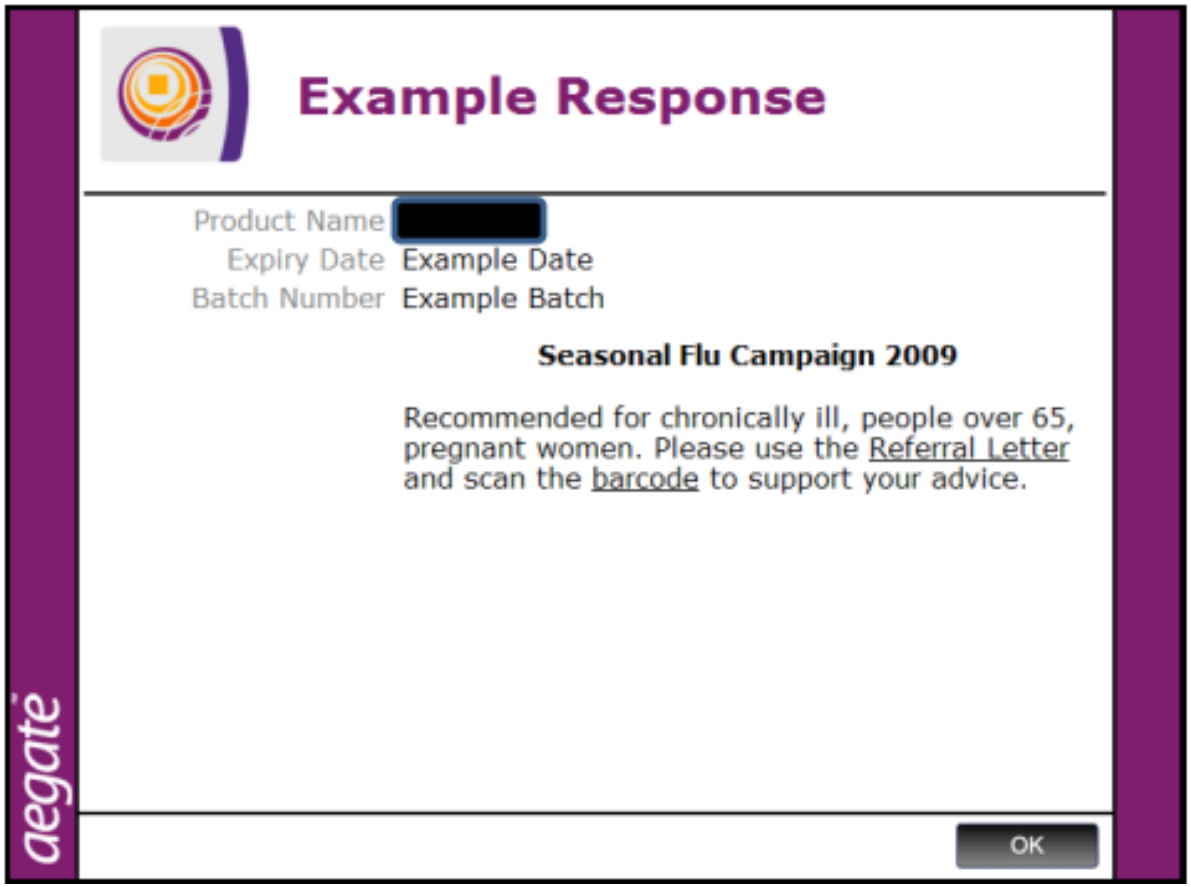
Pharmacy-Based Intervention in COPD patients



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

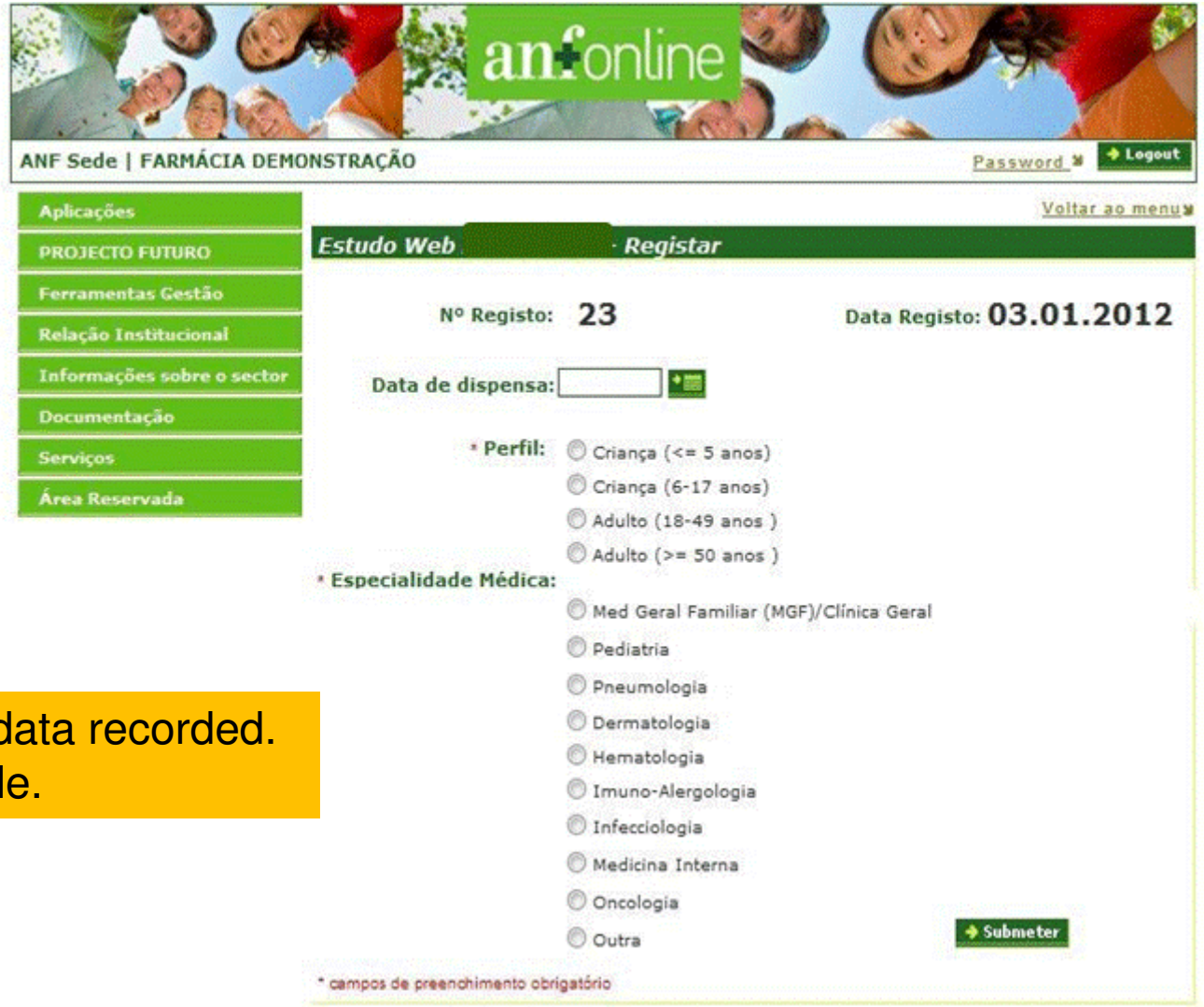
Torre C, Guerreiro JP, Madeira A, Lopes F, Mendes Z, Miranda A, Santos C, Costa S. *Pharmacy-Based Intervention in COPD patients – Portuguese Pharmacists can effectively improve inhalation technique!*. International Pharmaceutical Federation (FIP) Congress, Dublin, September, 2013.

Public Health Protection (Belgium)



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

Web Market Research Program in the Pharmacy (PORTUGAL)



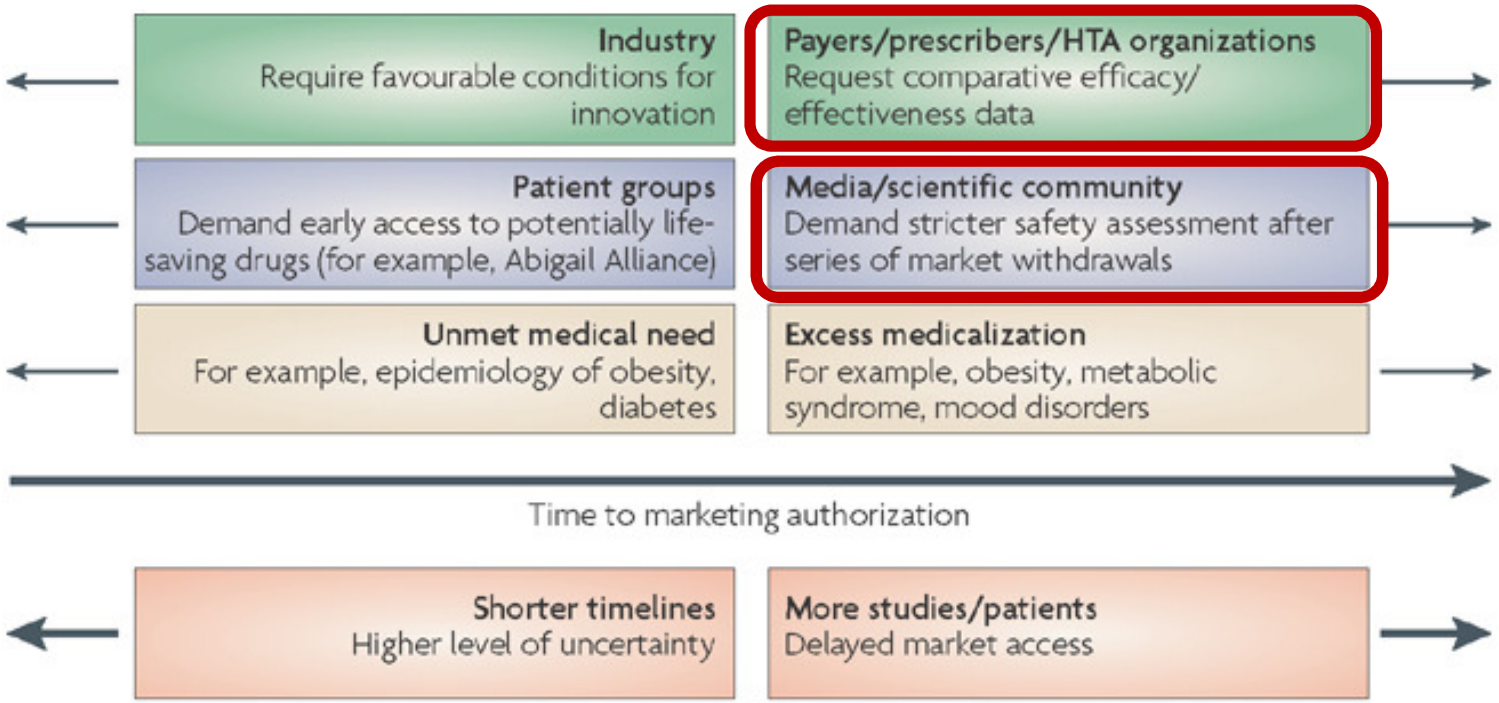
No safety data recorded.
But possible.

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

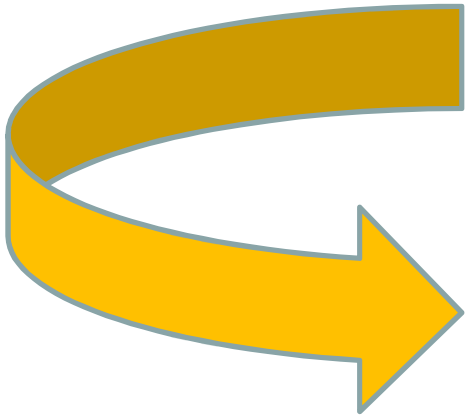


Nature Reviews | Drug Discovery

Eichler HG et al. Nature Rev Drug Disc 2008

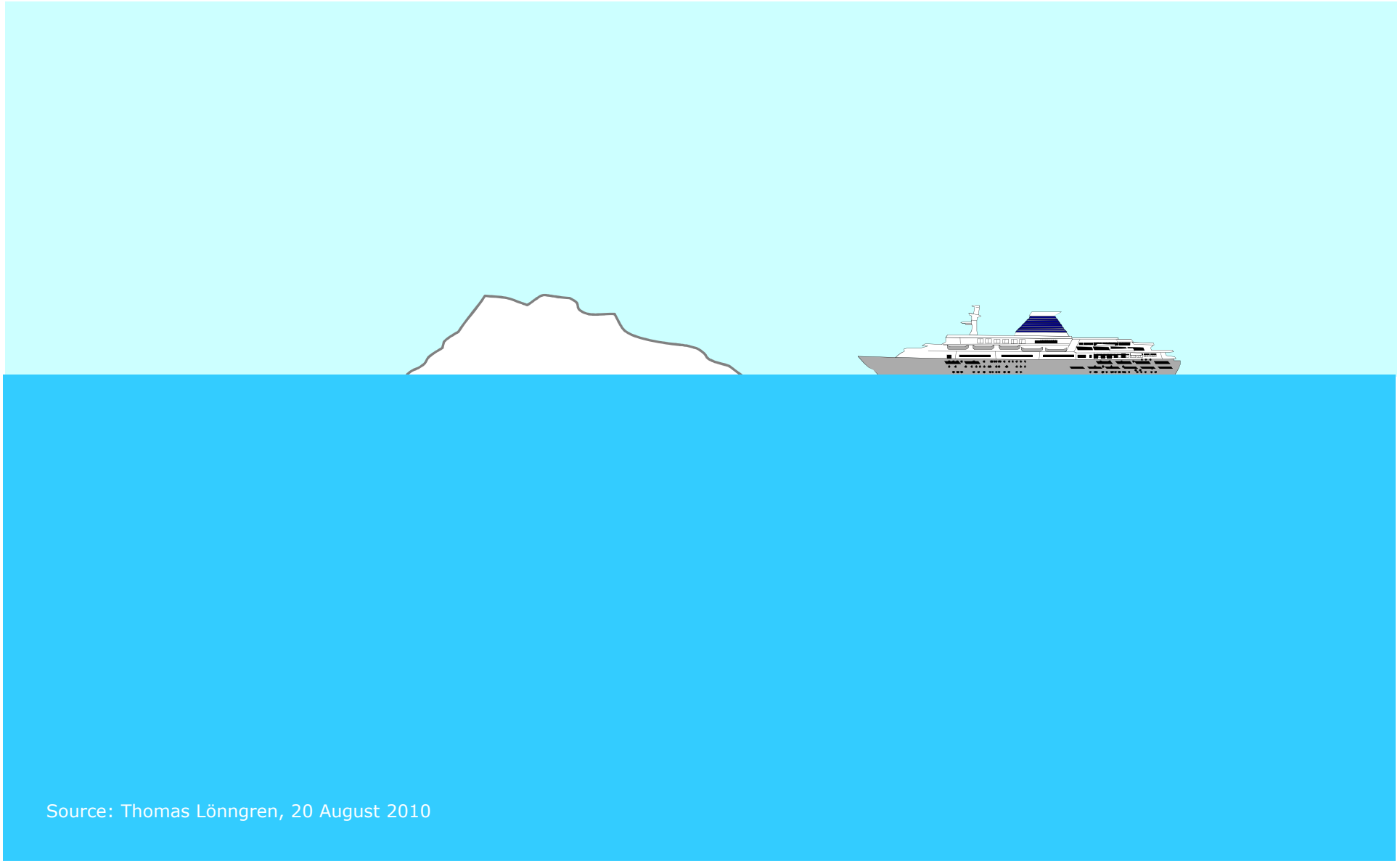
New Pharmacovigilance Legislation

Safety



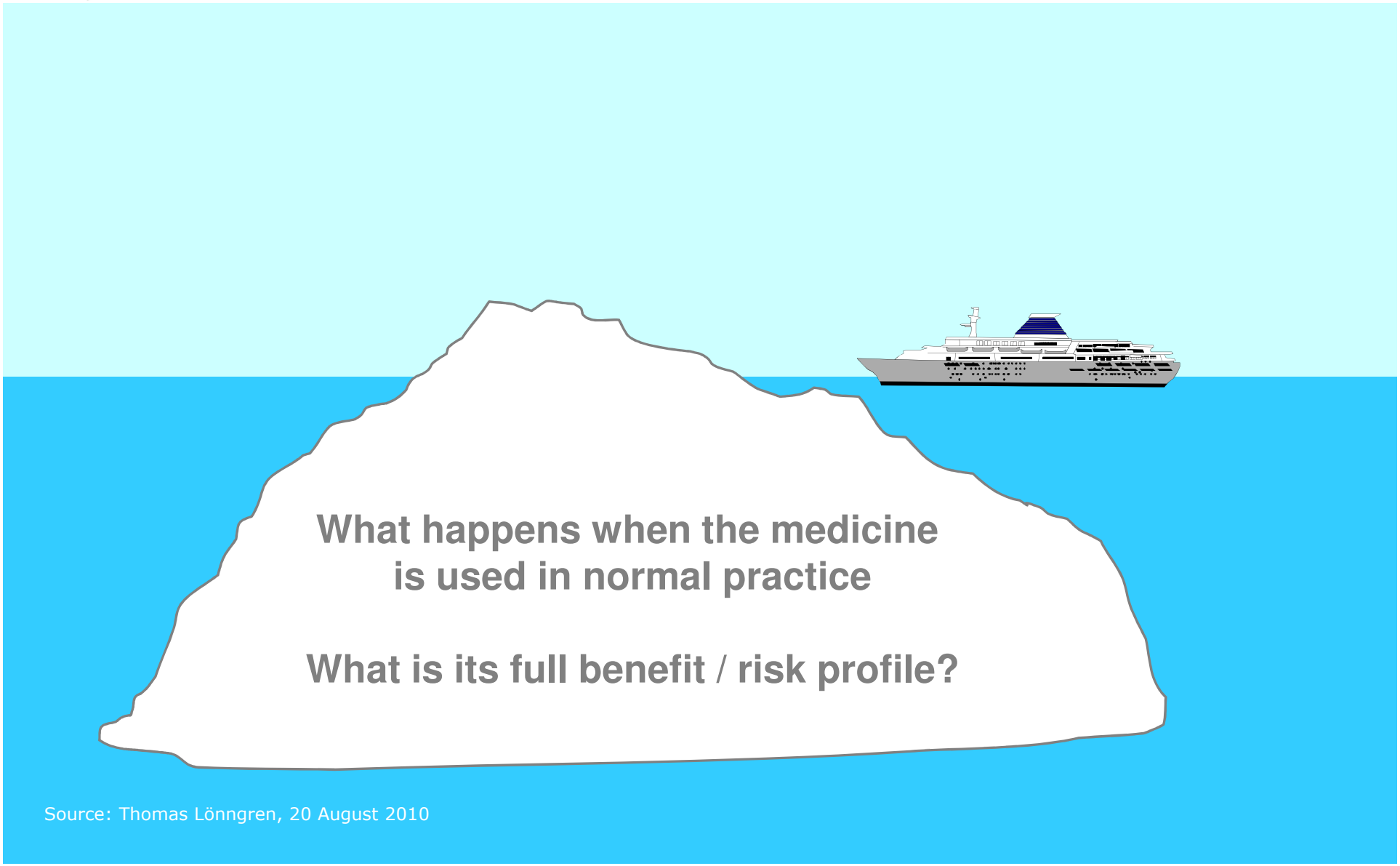
Benefit / Risk
assessment through the entire lifecycle of the Medicine

What we know at the time of authorization



Source: Thomas Lönngren, 20 August 2010

What we don't know…



Source: Thomas Lönngren, 20 August 2010

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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