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

Suzete Costa
Pharm D, MPH
Executive Director of the Centre for Health Evaluation & Research (CEFAR)
National Association of Pharmacies (ANF), PORTUGAL
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 ↑ 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
  - Patient Access Programs (Reimbursed by MAH)
    - No safety data
  - Adherence + Persistence

- When adding questionnaire + Pharmacist (qualified provider):
  - Spontaneous reporting
  - Managed Entry Programs, as per RMP
    - Designed to capture safety data
  - Observational Studies
    - Designed to capture safety data
    - (Post-authorization Study)
  - 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

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
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
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**

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

One third of study participants (63 out of 209) reported at least one AE.
Adherence and Persistence in Pharmacies (PORTUGAL)

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.

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

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

Industry
Require favourable conditions for innovation

Payers/prescribers/HTA organizations
Request comparative efficacy/effectiveness data

Patient groups
Demand early access to potentially life-saving drugs (for example, Abigail Alliance)

Media/scientific community
Demand stricter safety assessment after series of market withdrawals

Unmet medical need
For example, epidemiology of obesity, diabetes

Excess medicalization
For example, obesity, metabolic syndrome, mood disorders

Time to marketing authorization

Shorter timelines
Higher level of uncertainty

More studies/patients
Delayed market access

New Pharmacovigilance Legislation

Safety

Benefit / Risk assessment through the entire lifecycle of the Medicine
What we know at the time of authorization

Source: Thomas Lööngren, 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?

Source: Thomas Lönngren, 20 August 2010
Bridging the gap between RCT and Real-World – A call to Arms to the Community Pharmacies

   - 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

E-mail: Suzete.Costa@anf.pt