

Direct patient reporting

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Agenda

- a) The added value of direct consumer reporting
- b) The experience of two consumers' organizations in Italy and Belgium
- c) The role of patients' and consumers' organizations
- d) Expectations from the implementation of the new pharmacovigilance legislation



The added value

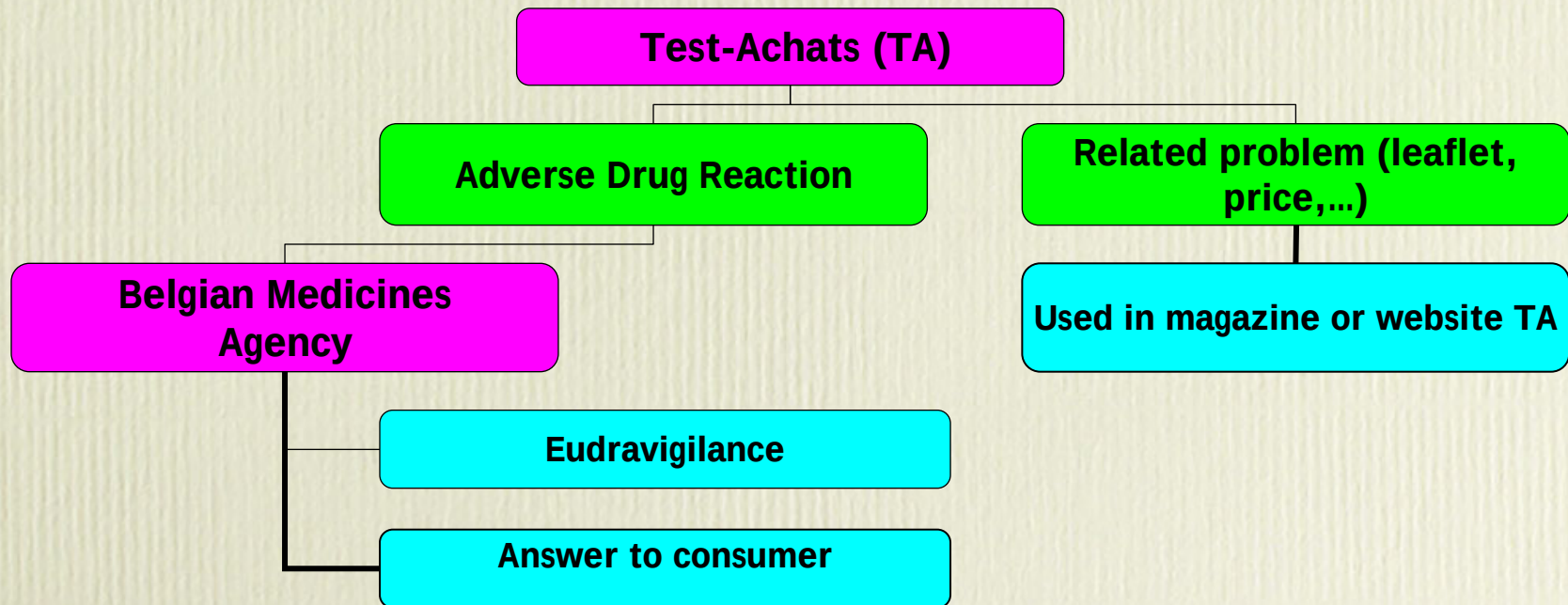
- Patient/consumer empowerment and involvement
- ADRs can be detected earlier
- More ADRs are reported (in quantity and variety)
- Better understanding of ADRs
- Complement report from health care professionals



The experience of Test-Achats

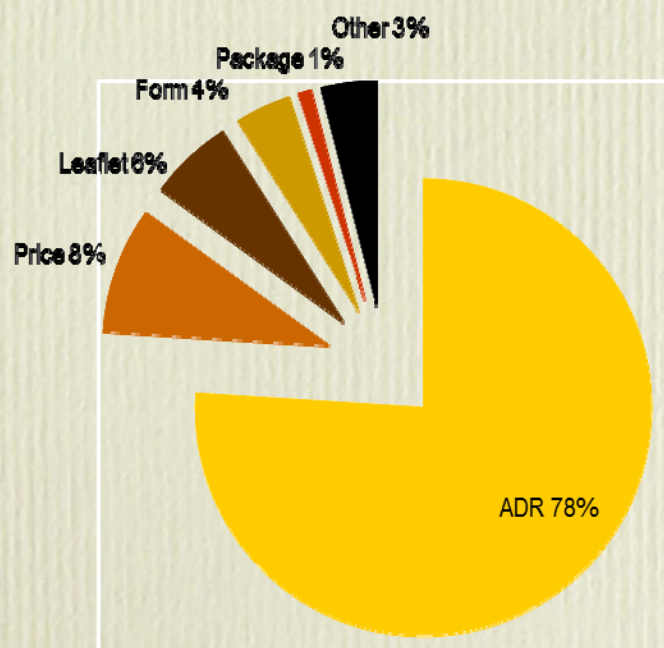
- WHEN: since November 2006
- WHAT: adverse drug reactions and other problems (e.g. leaflet, price, availability)
- HOW: internet and paper form (including phone line)
- WHO: Test-Achats in collaboration with Belgian Medicines Agency
- FORM: name of the medicine, indication, dose, ADR, when it started, other medications, other related problems (leaflet, reimbursement, format e.g. tablets too big to swallow, packaging e.g. too big for treatment period, demographic info, etc)

Analysis





Results (November 2006 to October 2010)



Total	Number
Reports	900
Problems (1 report / different problems)	1736
Adverse Drug Reaction	78%
Related problems	22%

Interesting results

- Information about the impact of the side effect(s) on people's daily lives. Patients asked to score the seriousness of the problem and the actions taken.
- Psychological or sexual ADRs usually not reported to health care professionals: 20 reports
- Reports about OTC medicines: 82 reports
- Report about herbal medicines, homeopathy, food supplements, etc.: 40 reports
- Unknown ADRs: 46%
- Consumer reports are correct and detailed
- Increased public awareness

Tell us your story...

- In collaboration with the Italian Medicine Agency
- Questionnaire on the website www.altroconsumo.it

A) Two treatments for atopic dermatitis

- Indicated as second line therapy in the treatment of atopic dermatitis. Only dermatologists can prescribe it. Should not be used for a long period of time and not in children < 2 years old.
- **Questions:** who prescribed it?, for what problem? after topical corticosteroids were unsuccessful? age of patient? any problem? did you use it for a long time? any comment?
- **Data collection period:** June 2006 – January 2009
- **Contacts :** 490

Results

- Off-label use :12
- Prescription as **first-line treatment**:185
- Prescribed by general practitioners: 51
- For children ≤ 2 years old: 49
- Used for a long time (≥ 3 months):135
- Suspected adverse drug reactions:**140**
- Official report from health care professionals to AIFA for the period 2001-2008: **14**

B) Treatment for severe acne

- Indicated for the second-line treatment of severe acne. Only dermatologists can prescribe it. Because of its teratogenic effect, pregnancy must be avoided during treatment.
- **Questions:** who prescribed it? For what problem? After the first-line treatment for acne was unsuccessful? Age and sex of patient? Information received? Follow-up? Satisfaction with the therapy? Adverse reactions? Any comment?
- **Data collection period:** April 2009 – September 2010
- **Contacts :** 276

Results

- **Severe acne: 150 Moderate: 69 Light:8 Others:49**
- **Prescription as first-line treatment:30**
- **Information on**
 - adverse effects: 210 yes 44 no 21 blank
 - blood donation: 106 yes 149 no 21 blank
 - doctor's suggestion to report ADR:
 215 yes 40 no 21 blank
 - blood tests during treatment:
 198 yes 52 no 26 blank
- **Adverse drug reactions: 193**

CONCLUSIONS

Consumers/Patients can play an important role in pharmacovigilance because they:

- ☐ Are those who directly experiences the problems
- ☐ Want to have a say in drug safety-related problems
- ☐ Report in a reliable and valid manner
- ☐ Give useful information about authorised use of medicines but also on MISUSE - less likely to be reported by health care professionals.

>salute

salute in famiglia

bambini

uomo

donna

anziani

starbene

cura personale

dalla testa ai piedi

mente e cervello

cuore e circolazione

bocca/stomaco/

intestino

reni/vescica/

utero/prostata

naso/polmoni

ossa/muscoli

udito/vista/pelle

focus su ...

tumori

diabete

infezioni virali

malattie genetiche e

autoimmuni

obesità/dimagrimento

allergie/intolleranze

cure e terapie

farmaci e generici

> salute > cure e terapie > farmaci e generici

aprile 2009

>parliamo di...

Farmaci ed erbe: non sempre sicuri. Segnala gli effetti indesiderati

Un farmaco ti ha provocato reazioni sgradite? Segnalalo in tre mosse

1. Scarica.

Quitrovi la [scheda](#) che i cittadini possono utilizzare per la comunicazione di effetti indesiderati, predisposta dal ministero della Salute.

2. Compila.

Per la compilazione della scheda vi consigliamo di farvi aiutare dal medico o del farmacista.

Se vi serve un aiuto, Altroconsumo offre una consulenza telefonica: telefonate allo **02.69.61.555, dal lunedì al venerdì 9-13 e 14-18.**

3. Spedisci.

La scheda poi deve essere spedita direttamente alla vostra Asl, all'ufficio del responsabile della farmacovigilanza.

Sul sito della farmacovigilanza.org (cliccate in home page sulla voce "Sedi e responsabili") si possono trovare gli indirizzi dei responsabili di farmacovigilanza delle Asl a cui inviare la scheda di segnalazione così come le schede per gli operatori sanitari.



⇒ **Farmaci ed erbe: non sempre sicuri. Segnala gli effetti indesiderati**

segnalare un farmaco

- Un farmaco ti ha provocato reazioni sgradite? Segnalalo in tre mosse
- Un prodotto a base di erbe ti ha provocato reazioni sgradite? Segnalalo in tre mosse
- Farmaci nuovi: la lista dei "sorvegliati speciali"
- Questa la racconto



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Expectations

- ❖ User friendly reporting system in all EU member states
- ❖ Reporting possible via multiple channels
- ❖ Patients and consumers organizations consulted in the definition of the concrete reporting modalities at EU and national level
- ❖ Public adequately informed about the benefits/risks of medicines and about the importance of reporting
- ❖ Health care professionals encouraged to report



THANK YOU

More information on
www.beuc.eu

EC register for interest representatives :
identification number 9505781573-45