Europharma - Konferencja „Pharmacovigilance w 2015 r. – nowa praktyka, szanse i zagrożenia”

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Nederlands Bijwerkingen Centrum
Netherlands Pharmacovigilance Centre

# The role and operation of consumer reporting in the Netherlands

**Pharmacovigilance in 2015**

**Current perspectives and future challenges**

December 2, 2014

Dr. Linda Härmark, PharmD

WHO Collaborating Centre for Pharmacovigilance in Education and Patient reporting

www.lareb.nl

Consumer reporting

Patient reporting

Reporting from the general public

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# Definition consumer reporting

A consumer report is a report of a suspected adverse reaction to a medicinal product as initiated by the consumer and without interpretation by a health-care professional.

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# Why consumer reporting?

CURRENT OPINION

Drug Safety 2003; 26 (4): 211-217
0114-5916/03/0004-0211/$30.00/0



## Consumer Adverse Drug Reaction Reporting

### A New Step in Pharmacovigilance?

*Kees van Grootheest,*[1] *Linda de Graaf*[1] and *Lolkje T.W. de Jong-van de*

1 Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Neth
2 Department of Social Pharmacy and Pharmacoepidemiology, Groningen U
for Drug Exploration, Groningen, The Netherlands

**Abstract** The direct reporting of adverse drug reactions b
increasingly important topic for discussion in the w

Review

General

## Patients' role in reporting adverse drug reactions

Kees van Grootheest† & Lolkje de Jong-van den Berg
†*The Netherlands Pharmacovigilance Centre Lareb, Goudsbloemvallei 7, 5237 MH 's-Hertogenbosch, The Netherlands*

## Patient reporting of suspected adverse drug reactions: a review of published literature and international experience

A. Blenkinsopp,[1] P. Wilkie,[2] M. Wang[3] & P. A. Routledge[4]

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# Trial consumer reporting 2003

- In April 2003 trial with accepting consumer reports
- First year almost 300 consumer reports
- The reports from consumers contained enough medical information to be useful to pharmacovigilance

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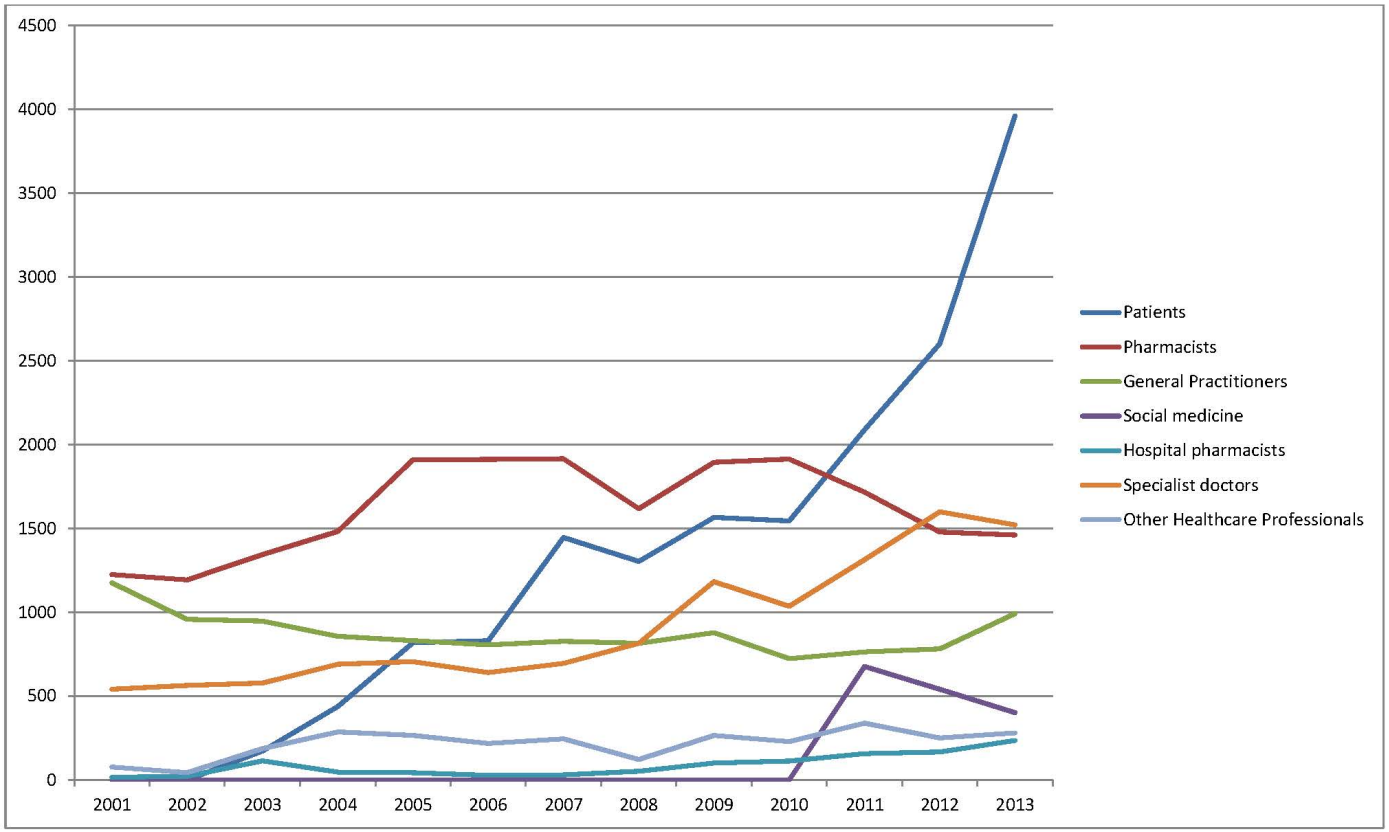
# Number of reports 2000 -2013



# WHAT IS THE CONTRIBUTION OF PATIENT REPORTS TO PHARMACOVIGILANCE?

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# Three years of experience with consumer reporting in the Netherlands

- Similarities found in age, sex, most frequently reported ADRs and most frequently reported drugs
- Differences between consumer- and healthcare professional reports in the categories of seriousness and outcome of the reported ADRs

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# Consumer's motivation for reporting ADRs

- Consumer characteristics of reporters
- *Altruism* is an important factor for reporting ADRs
- The *severity of ADR* and *need to share experiences* the main motives to report

van Hunsel F, *et al.* What Motivates Patients to Report an Adverse Drug Reaction? Ann Pharmacother 2010; 44(5):936-937

van Hunsel F, *et al.* Motives for reporting adverse drug reactions by patient-reporters in the Netherlands. Eur J Clin Pharmacol. 2010; 66:1143–1150.

# Consumers’s quotes about motives for reporting

…my motive is that this is information that has to be available to others and as Lareb collects this information I will report it to them. For me personally reporting doesn’t make a difference, I want to recover, and I will arrange that with my general practitioner. But this reaction could also happen to someone else and that should be known. So again it’s about making the adverse reaction known and taking care that the information is available…

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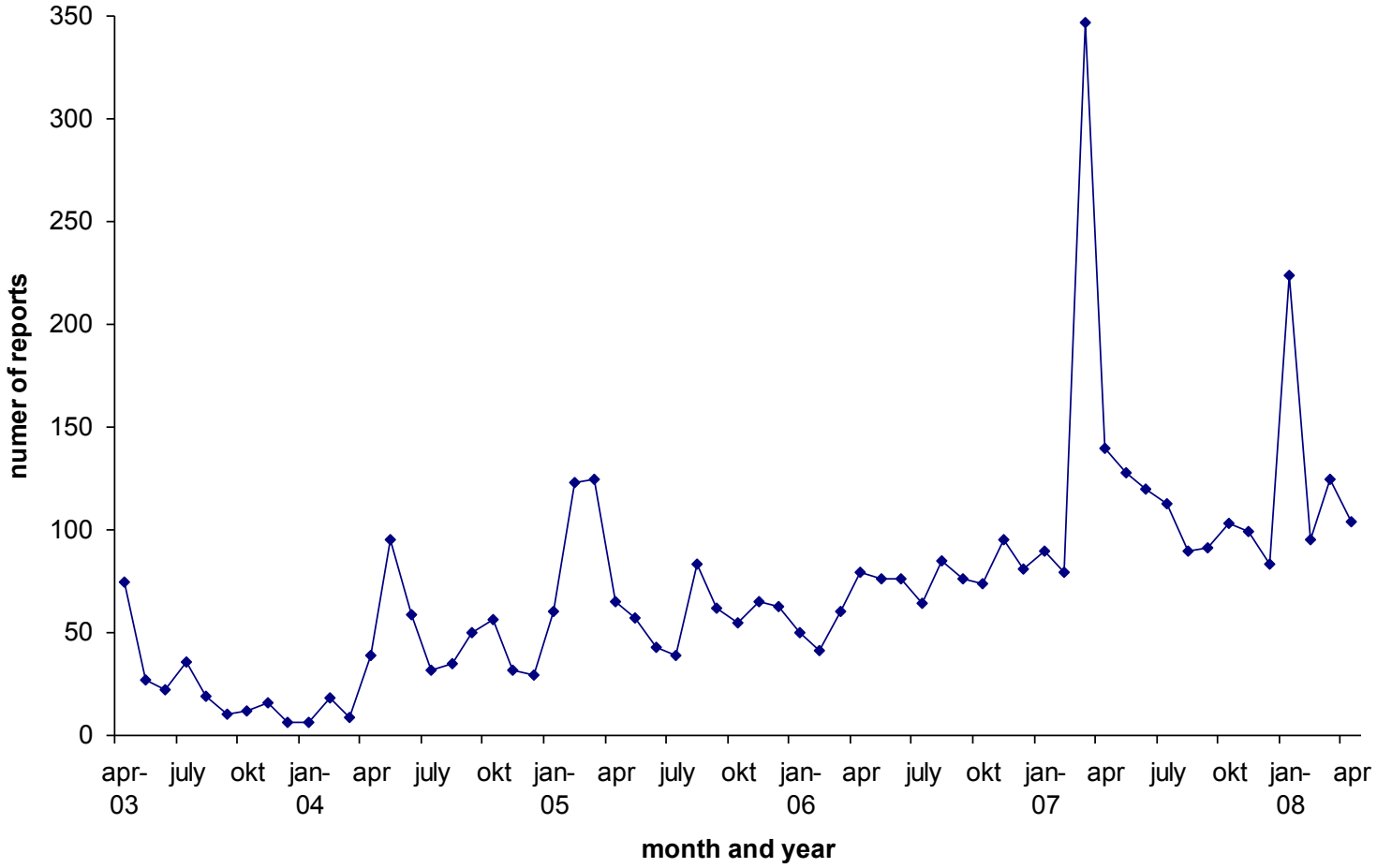
# Influence of media attention on consumer reporting



# Comparison consumer and HP reports after media attention

- Media attention led to a peak in consumer reporting of ADRs but not in reporting by health professionals

- Qualitative analysis**: Impact on quality of life** through consumer reports!

van Hunsel F, *et al.* Comparing patients' and healthcare professionals' ADR reports after media attention: the broadcast of a Dutch television programme about the benefits and risks of statins as an example. Br J Clin Pharmacol 2009; 67(5):558-564.

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# Contribution of consumer reporting to signal detection

- Consumers contribute to disseminated signals about drug-ADR associations
- Consumers’ reports of ADRs can provide a valuable contribution to the detection of signals
- This is ***additional*** to healthcare professionals’ reports

van Hunsel F,*et al.* The proportion of patient reports of suspected ADRs to signal detection in the Netherlands: case-control study. Pharmacoepidemiol Drug Saf 2011; 20(3): 286–291.

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# Signal detection

- Duloxetine and electric shock sensation

# Signal detection

- Duloxetine and electric shock sensation
- SSRIs and persistant sexual dysfunction

# Signal detection

- Duloxetine and electric shock sensation
- SSRIs and persistant sexual dysfunction
- Cyproterone/ethinylestradiol and thromboembolic events

# Signal detection

- Duloxetine and electric shock sensation
- SSRIs and persistant sexual dysfunction
- Cyproterone/ethinylestradiol and thromboembolic events
- Changes in packaging of levothroxine and ADRs

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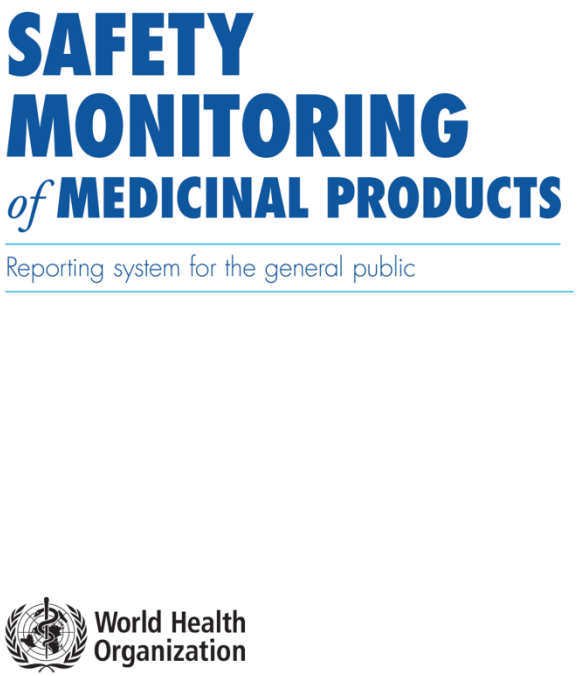
# EU legislation 2010

- Strengthen the European pharmacovigilance system
- Direct consumer reporting to national centers
- Implementation July 2012

Borg JJ *et al.* Strengthening and Rationalizing Pharmacovigilance in the EU: Where is Europe Heading to? Drug Saf 2011;34(3):187-197

# Guideline

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- 2. Definitions
- 3. How to start a consumer reporting system
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- 7. Assessment of case reports
- 8. Use of the data
- 9. Relations with other parties

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# How to start a consumer reporting system

- A functional spontaneous reporting system for health-care professionals as a basis.
  - Staff with knowledge in handling spontaneous reports are already available
  - A reporting form has already been developed and can be adapted for consumer reporting
  - Procedures for assessing reports have already been established
  - A database for storing reports is probably available

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# How to start a consumer reporting system

- Get health authorities and consumer and patient organizations on board

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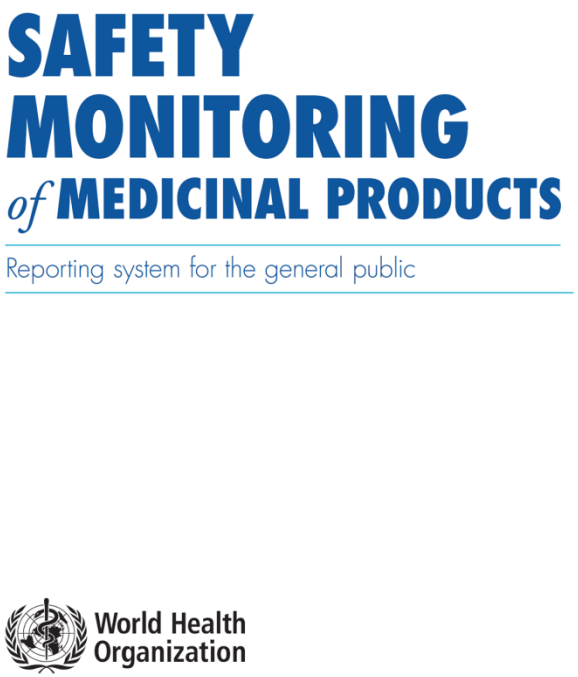
# Guideline

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# Means of reporting

**Table III.** Method of adverse drug reaction report collection per country

| Country | Telephone | Electronic forms | Paper forms |
|---|---|---|---|
| Australia | ✓ | ✓ | ✓ |
| Canada | ✓ | ✓ | ✓ |
| Denmark | | ✓ | |
| Malaysia | ✓ | | ✓ |
| Netherlands | | ✓ | |
| New Zealand | ✓ | ✓ | ✓ |
| Norway | | ✓ | |
| Philippines | ✓ | | ✓ |
| Sweden | | ✓ | ✓ |
| UK | ✓ | ✓ | ✓ |
| US | ✓ | ✓ | ✓ |

✓ indicates method of reporting available.

*Van Hunsel et al. Drug Safety 2012; 35 (1):45-60*

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# Reporting form

- Accessibility
- Content

**Table IV.** Specifications for electronic reporting forms[a]

| Country | Use of free-text in form | Mandatory fields in form | Forms automatically imported in database | Drop-down lists for selection of ADRs used in form | Drop-down list for selection of (co-) medication used |
|---|---|---|---|---|---|
| Australia (TGA) | Available | Available | Unknown | Not available | Not available |
| Australia (AME-Line) | Available | Not available | Not available | Not available | Not available |
| Canada | Available | Available | Not available | Not available | Not available |
| Denmark | Available | Available | Not available[b] | Not available | Available |
| Netherlands | Available | Available | Available | Not available | Available |
| New Zealand | Available | Not available | Not available | Not available | Not available |
| Norway | Available | Available | Available | Not available | Available |
| Sweden | Available | Available | Available | Not available | Not available |
| UK | Available | Available | Available | Available | Available |
| US | Available | Available | Unknown | Not available | Not available |

a Electronic patient reporting forms were not available for Malaysia and the Philippines.

b At the time of the interview, the forms were not automatically imported in the database; in the new system that the Danish Medicines Agency uses, this will have changed.

**ADRs** = adverse drug reactions; **AME** = Adverse Medicines Events; **TGA** = Therapeutic Goods Administration.

*Van Hunsel et al. Drug Safety 2012; 35 (1):45-60*

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Drug Saf (2014) 37:409–419
DOI 10.1007/s40264-014-0162-y

ORIGINAL RESEARCH ARTICLE

# Adverse Drug Reaction Reporting by Patients: An Overview of Fifty Countries

Florence Margraff · Delphine Bertram

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- Different forms for HCPs and consumers
- Different forms for drugs and vaccines

# Reporting of adverse drug reactions to medicines

- Means of reporting
- Reporting form
- What to report

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# What to report?

- ADRs of registered drugs

- Medications errors
- Counterfeit drugs
- Herbals and vitamines

# Promotion

- Increase awareness

  of the possibililty: you can!

  of the importance: you should!

- General

- Targeted

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# Magazine


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# Promotion


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# Promotion

- General
- Targeted

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**geef uw mening**

12-09-2014
Vrouw (43) - Anticonceptie...

**Mirena spiraal (levonorgestrel)**

Algehele tevredenheid:

In nov 2009 is bij mij het mirena spiraaltje geplaatst. Ik heb ong 2jaar last gehad van bloedingen, te pas en te onpas. Na Meerdere keren, vd huisarts medicatie gehad om het bloeden te laten stoppen was het na zon 2 jaar dan eindelijk over. Toen een jaar lang zo af en toe een bloeding en daarna ruim 1 1/2 jaar helemaal niets meer. Sinds een tijdje heb ik een rare gee [lees meer...]

Tevredenheid over
- Effectiviteit
- Hoeveelheid bijwerkingen
- Ernst bijwerkingen
- Inname- / gebruiksgemak

Reageer op deze ervaring

12-09-2014
Vrouw (48) - Overgang

**Mirena spiraal (levonorgestrel)**

Algehele tevredenheid:

I.v.m. hevig vloeien met stolses met als gevolg een heel laag hb tijdens de overgang werd een Mirenaspiraal geplaatst door de gynaecoloog. Het inbrengen verliep snel en pijnloos (tot verbazing van de gynaecoloog). De menstruaties werden minder en bleven na een paar maanden weg. Na een half jaar begonnen bijwerkingen; ineens afvallen, extreem rusteloos gevoel, depressief, n [lees meer...]

Tevredenheid over
- Effectiviteit
- Hoeveelheid bijwerkingen
- Ernst bijwerkingen
- Inname- / gebruiksgemak

1 Reactie

Kijk hier voor informatie over zwangerschap.

**LET OP!**

Ervaringen zijn persoonlijk en de werking van medicijnen verschilt per persoon. Raadpleeg altijd uw arts en/of apotheker voor passend advies.
Zie ook bij « veelgestelde vragen » het doel van mijnmedicijn.nl.

# Consumer and patient organisations

- Questionnaires
- Screening of reported ADRs
- Respondents asked to fill in the reporting form

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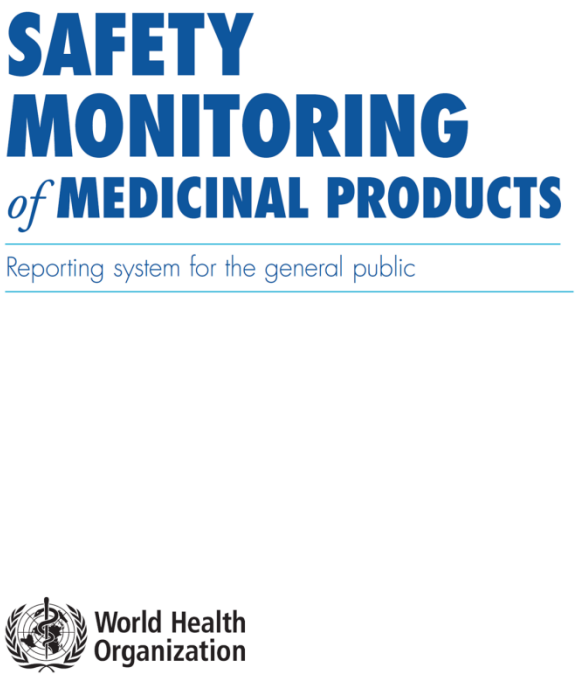
# Consumer and patient organisations

- Good respons (25%)
- Willingness to provide follow up information
- Reports contribute to signal detection

# Guideline

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# Handling of consumer ADR reports

- Differences in route of handling
  - Coding
  - Assessment
  - Feedback
  - Follow-up

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# Example of Feedback from NL

**Dear (name reporter),**
**Thank you for reporting to the Netherlands Pharmacovigilance Centre Lareb. Your report has been registered under the number 12345.**

*Lareb recently published about aggressive behavior during the use of antidepressant medication (SSRIs). Aggressive behavior is described in the official information leaflet of fluoxetine. This reaction is mainly seen in users under 18 years. The extent to which adverse drug reaction occur and which adverse drug reactions occurs varies per person. Unfortunately this cannot be predicted. Recovery of the aggressive behavior after withdrawal of fluoxetine is an indication for a causal relation.*

**Your report will be included in the Lareb database. This is a database in which all adverse drug reactions of all drugs in the Netherlands are collected. In this way, Lareb gets a good overview of the safety of medicines and will take action if necessary.**
**Thank you again for reporting.**
**Best regards,**

Lareb

# Handling of consumer ADR reports

- Differences in route of handling
  - Coding
  - Assessment
  - Feedback
  - Follow-up
- Duplicate detection
- Sharing reports with international databases
- Signal detection

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- The role of the patient in pharmacovigilance
- The added value of patient reports to pharmacovigilance
- Maintaining and developing patient reporting systems
- Promoting patient reporting systems

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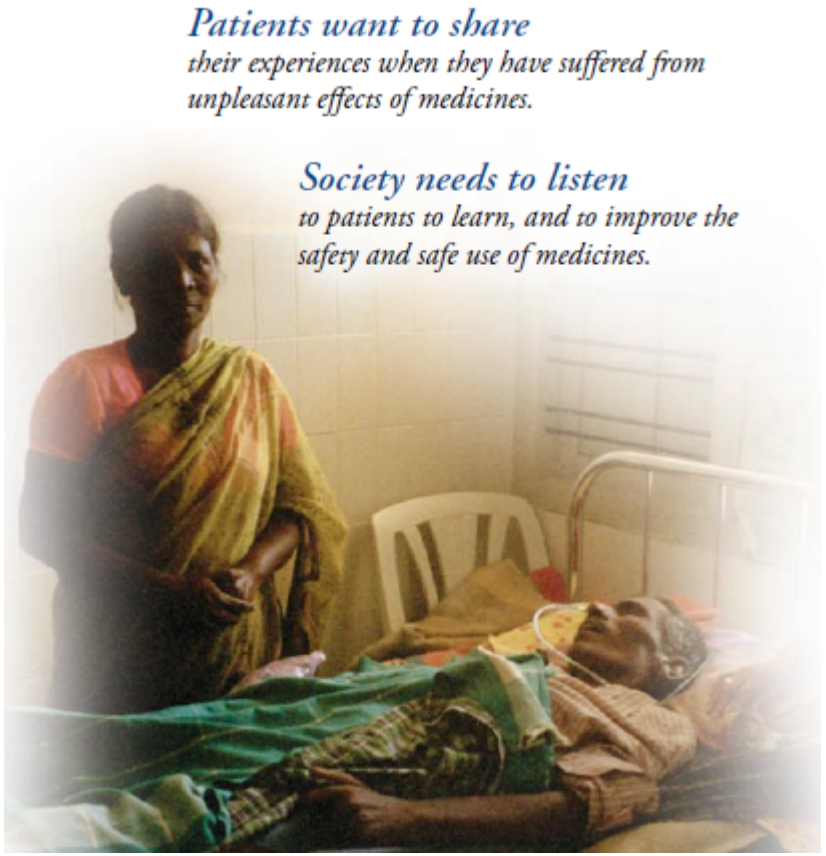
# Take home message

- Consumer reporting of ADRs helps to broaden our insights on the safety of drugs, which is ultimately the goal of all our pharmacovigilance activities

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