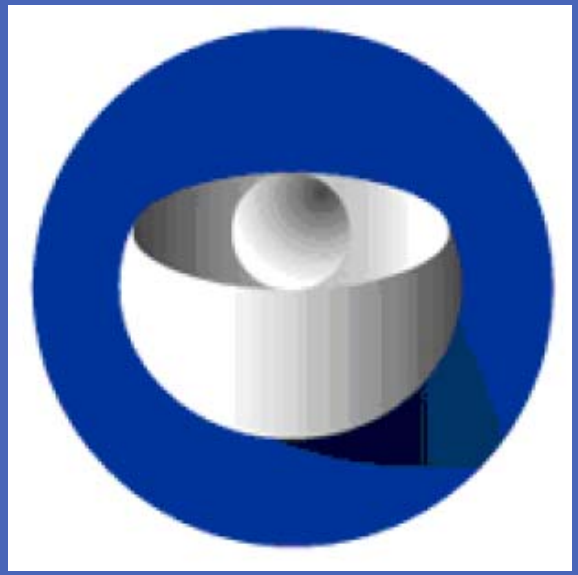
Direct Patient Reporting
DPR: The Dutch case



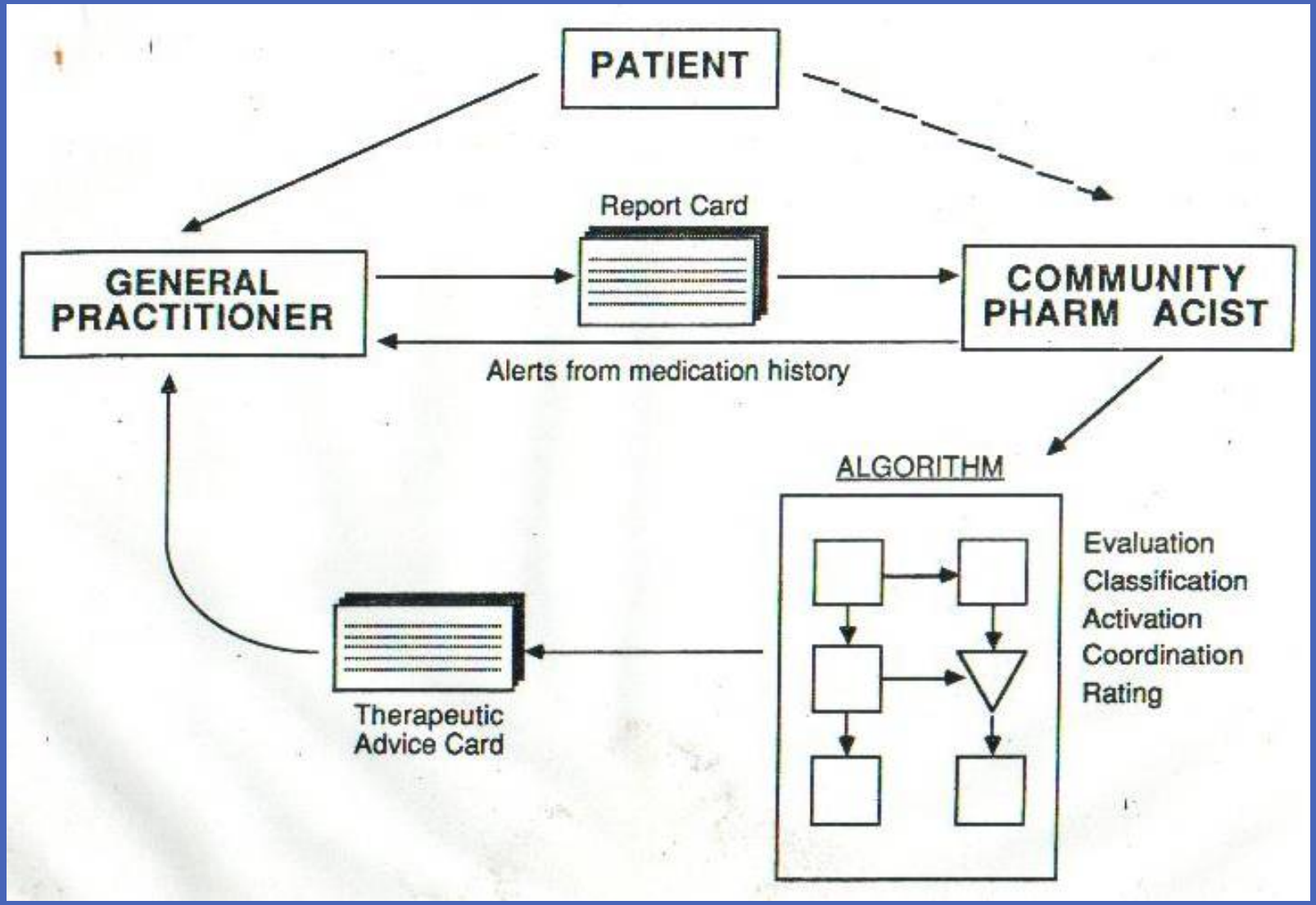
Fred de Koning

London, june 17th 2011

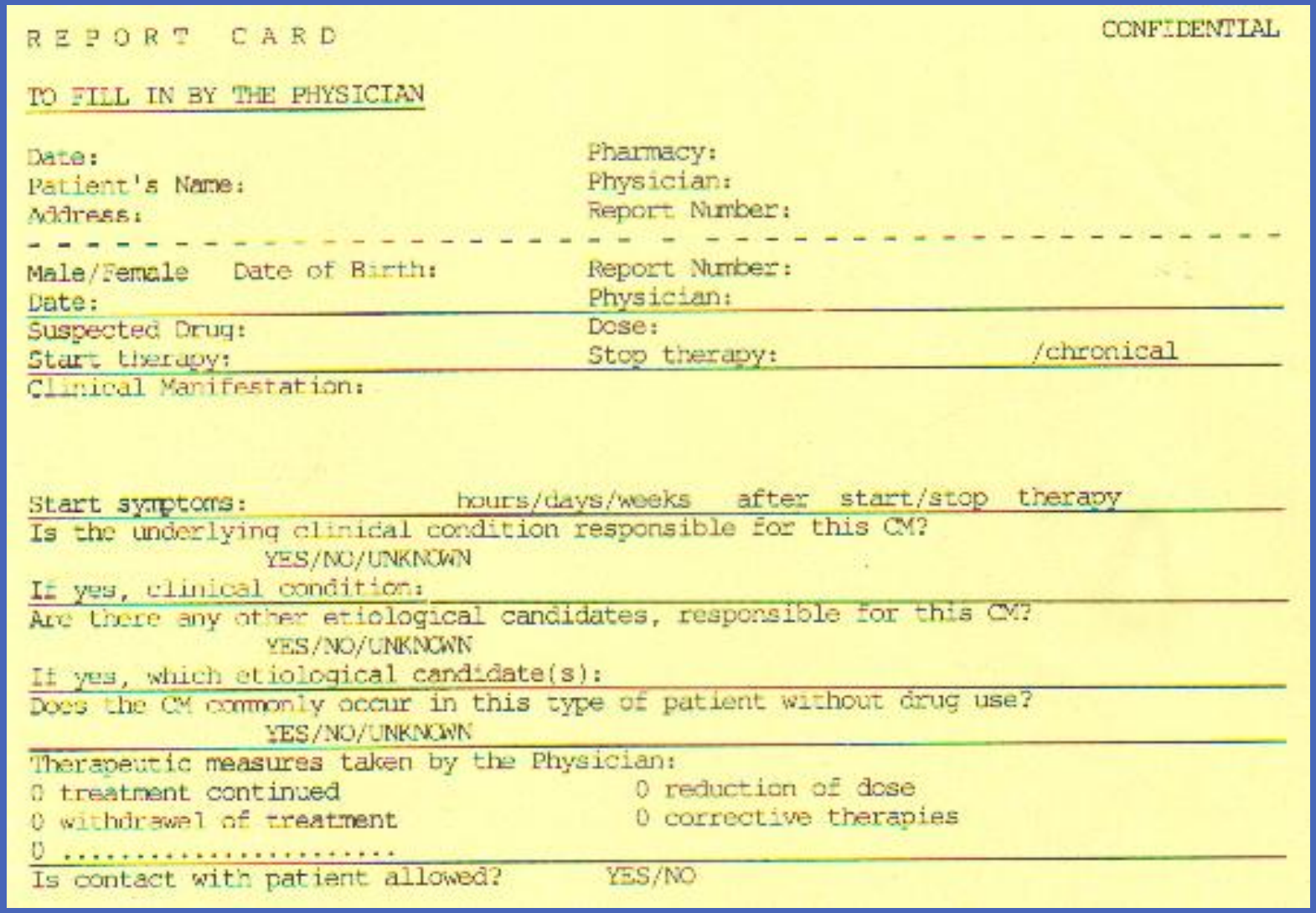
INTRODUCTION

- History
- Reasons for DPR?
- Reporting
- Feedback
- Facts & Figures

HISTORY


PATIENT
Report Card
GENERAL PRACTITIONER
COMMUNITY PHARM ACIST
Alerts from medication history
ALGORITHM
Evaluation
Classification
Activation
Coordination
Rating
Therapeutic Advice Card

HISTORY



REPORT CARD CONFIDENTIAL

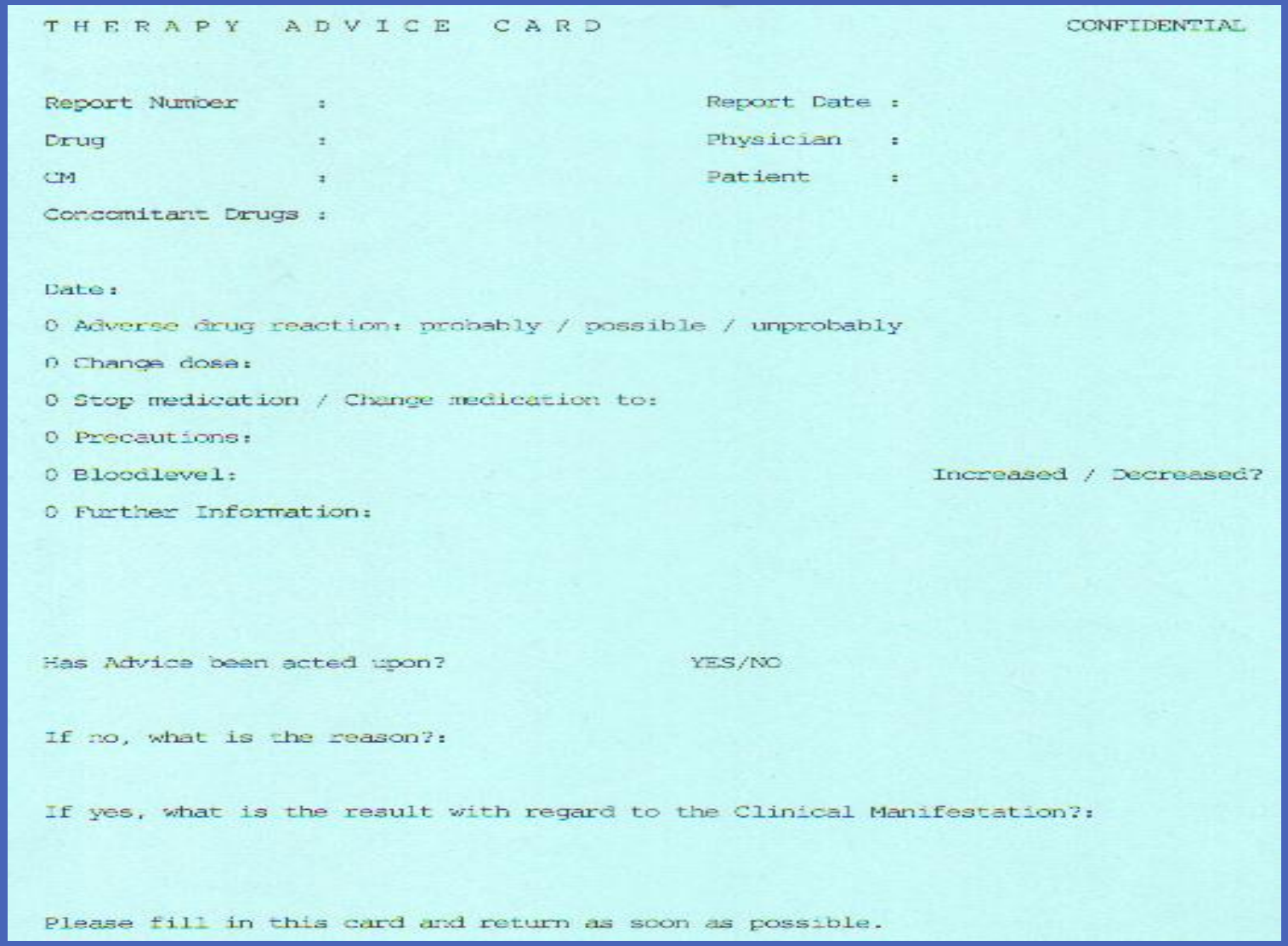
TO FILL IN BY THE PHYSICIAN

Date: Pharmacy:
Patient's Name: Physician:
Address: Report Number:

Male/Female Date of Birth: Report Number:
Date: Physician:
Suspected Drug: Dose:
Start therapy: Stop therapy: /chronical
Clinical Manifestation:

Start symptoms: hours/days/weeks after start/stop therapy
Is the underlying clinical condition responsible for this CM?
YES/NO/UNKNOWN
If yes, clinical condition:
Are there any other etiological candidates, responsible for this CM?
YES/NO/UNKNOWN
If yes, which etiological candidate(s):
Does the CM commonly occur in this type of patient without drug use?
YES/NO/UNKNOWN
Therapeutic measures taken by the Physician:
0 treatment continued 0 reduction of dose
0 withdrawel of treatment 0 corrective therapies
0 .....
Is contact with patient allowed? YES/NO

HISTORY



THERAPY ADVICE CARD CONFIDENTIAL

Report Number : Report Date :

Drug : Physician :

CM : Patient :

Concomitant Drugs :

Date:

0 Adverse drug reaction: probably / possible / unprobably

0 Change dose:

0 Stop medication / Change medication to:

0 Precautions:

0 Bloodlevel: Increased / Decreased?

0 Further Information:

Has Advice been acted upon? YES/NO

If no, what is the reason?:

If yes, what is the result with regard to the Clinical Manifestation?:

Please fill in this card and return as soon as possible.

REASONS

- Evidence based practice
- Optimizing medication safety, by risk/benefit monitoring
- Signal detection - timely detection of unknown ADRs

REASONS

Eur J Clin Pharmacol

Table 1 Statements used in the questionnaire to assess the reasons for reporting an adverse drug reaction (ADR) and the opinions of patients regarding the reporting of an ADR

Reasons
I wanted extra information
The adverse drug reaction was severe
It was difficult to discuss the adverse drug reaction with my medical practitioner or pharmacist
The possibility for reporting an adverse drug reaction just exists
I wanted to be heard
Someone else pointed the possibility for reporting an adverse drug reaction
I was angry about the situation
I wanted action to be taken
I wanted to share my experiences
The adverse drug reaction was not mentioned in the patient information leaflet
I was worried about my own situation
Opinions
Reporting an adverse drug reaction can prevent harm to other people
I felt responsible for reporting an adverse drug reaction
Reporting an adverse drug reaction that is already mentioned in the patient information leaflet is useless
I only report an adverse drug reaction if it is serious
Reporting an adverse drug reaction contributes to research and knowledge
I report an adverse drug reaction if it is not mentioned in the patient information leaflet
I benefit from reporting an adverse drug reaction
Reporting an adverse drug reaction contributes to improvement of drugs
I report an adverse drug reaction if it is unexpected
In the future I will report a possible adverse drug reaction once again

Hunsel Van et. Al. Eur J Clin Pharmacol 2010

REASONS

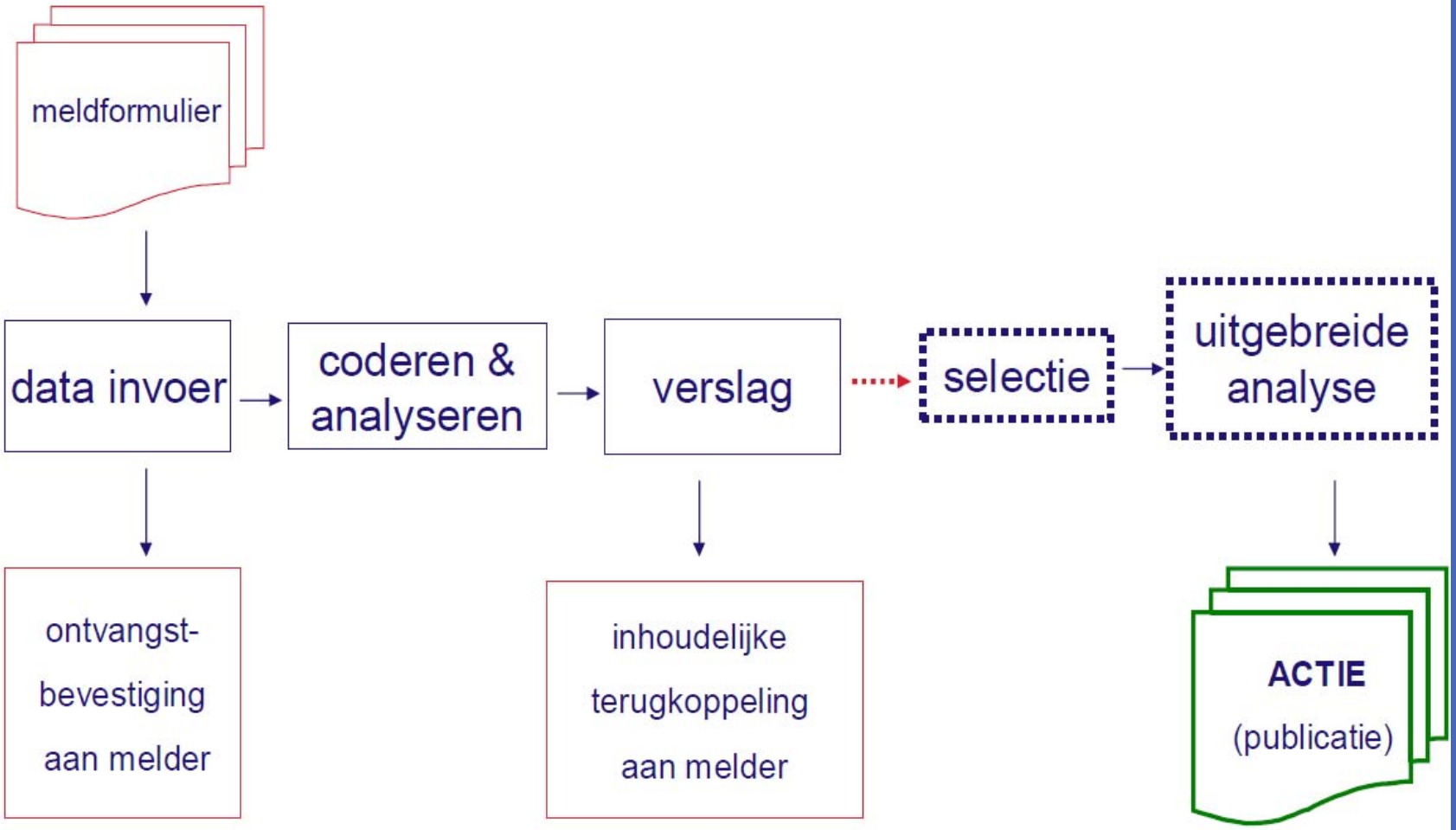
Eur J Clin Pharmacol

Table 3 Motives for reporting ADRs

Motive	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I wanted extra information	19.6% (196)	25.2% (252)	22.2% (222)	17.9% (179)	15.0% (150)
The adverse drug reaction was severe	53.7% (536)	32.5% (325)	8.2% (82)	3.5% (35)	2.1% (21)
It was difficult to discuss the adverse drug reaction with my medical practitioner or pharmacist	6.0% (60)	9.3% (93)	15.8% (158)	34.5% (345)	34.3% (343)
The possibility for reporting an adverse drug reaction just exists	34.7% (347)	38.0% (380)	17.9% (179)	5.6% (56)	3.7% (37)
I wanted to be heard	25.1% (251)	28.4% (284)	26.4% (264)	12.7%(127)	7.3% (73)
Someone else pointed the possibility for reporting an adverse drug reaction	14.9% (149)	17.1% (171)	14.2% (142)	28.7% (287)	25.0% (250)
I was angry about the situation	20.7% (207)	18.9% (189)	20.5% (205)	22.7% (227)	17.1% (171)
I wanted action to be taken	27.3% (273)	31.0% (310)	23.6% (236)	11.0% (110)	7.0% (70)
I wanted to share my experiences	48.1% (481)	40.9% (409)	6.3% (63)	2.8% (28)	1.8% (18)
The adverse drug reaction was not mentioned in the patient information leaflet	33.2% (332)	24.4% (244)	17.5% (175)	17.1% (171)	7.7% (77)
I was worried about my own situation	32.5% (325)	30.7% (307)	17.5% (175)	12.2% (122)	7.0% (70)

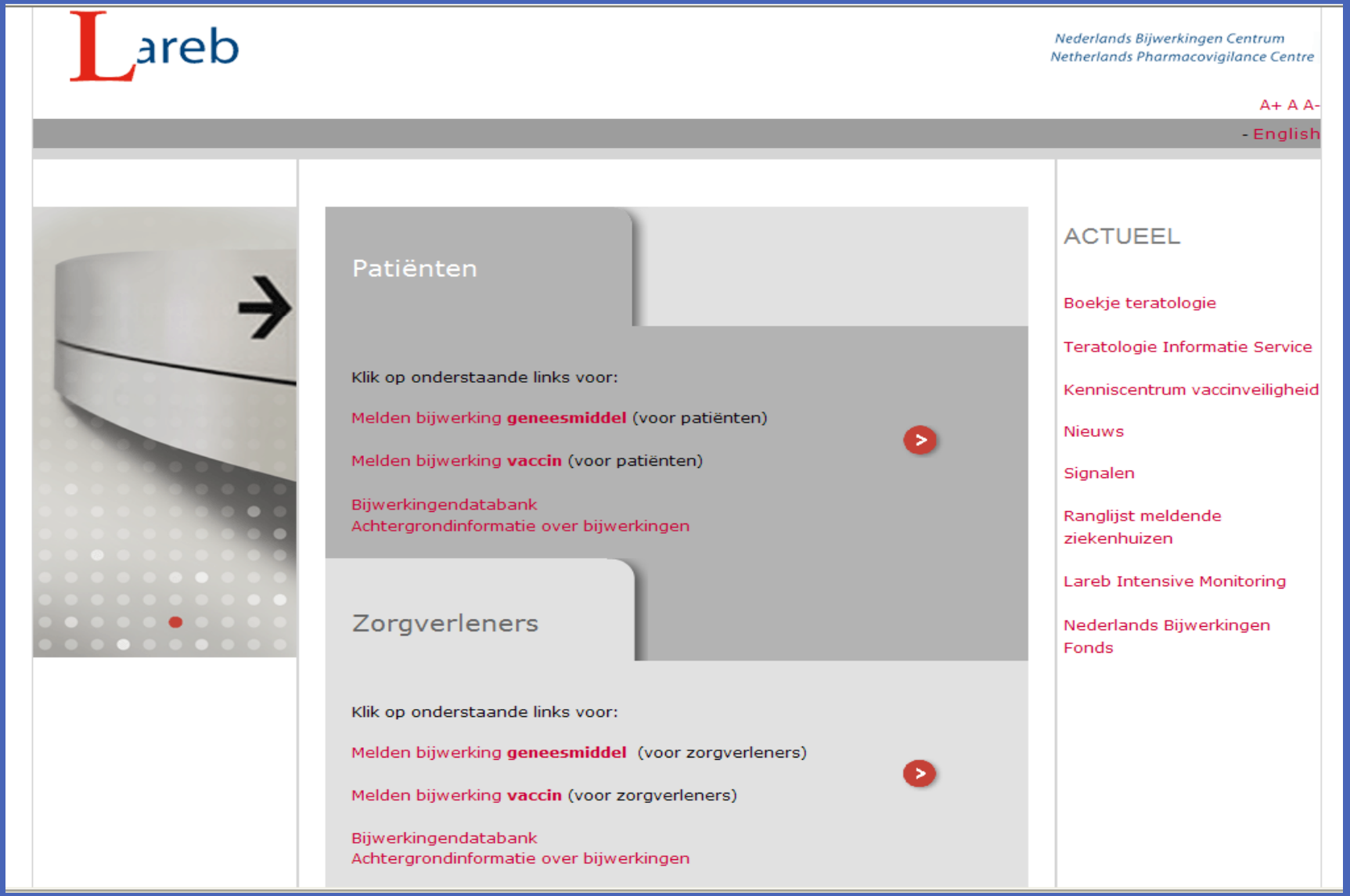
Hunsel Van et. Al. Eur J Clin Pharmacol 2010

ROUTING OF A REPORT



REPORTING

WWW.LAREB.NL



REPORTFORM

PART 1

Lareb

Nederlands Bijwerkingen Centrum
Netherlands Pharmacovigilance Centre

MELDFORMULIER PATIENT

Tel (073) 646 9700 fax (073) 6426136 info@lareb.nl

NB: DIT IS HET MELDFORMULIER VOOR GEBRUIKERS VAN GENEESMIDDELEN.
Bent u een zorgverlener, vul dan het meldformulier voor zorgverleners in.

INLEIDING

Met de help-knop (i) kunt u meer informatie over de vraag bekijken. Onderaan dit formulier kunt u aanvullende gegevens of een uitgebreide beschrijving van de klachten kwijt.

Noodzakelijke velden zijn gemarkeerd met een sterretje (*).

Melddatum: 15-6-2011

A BIJWERKINGEN

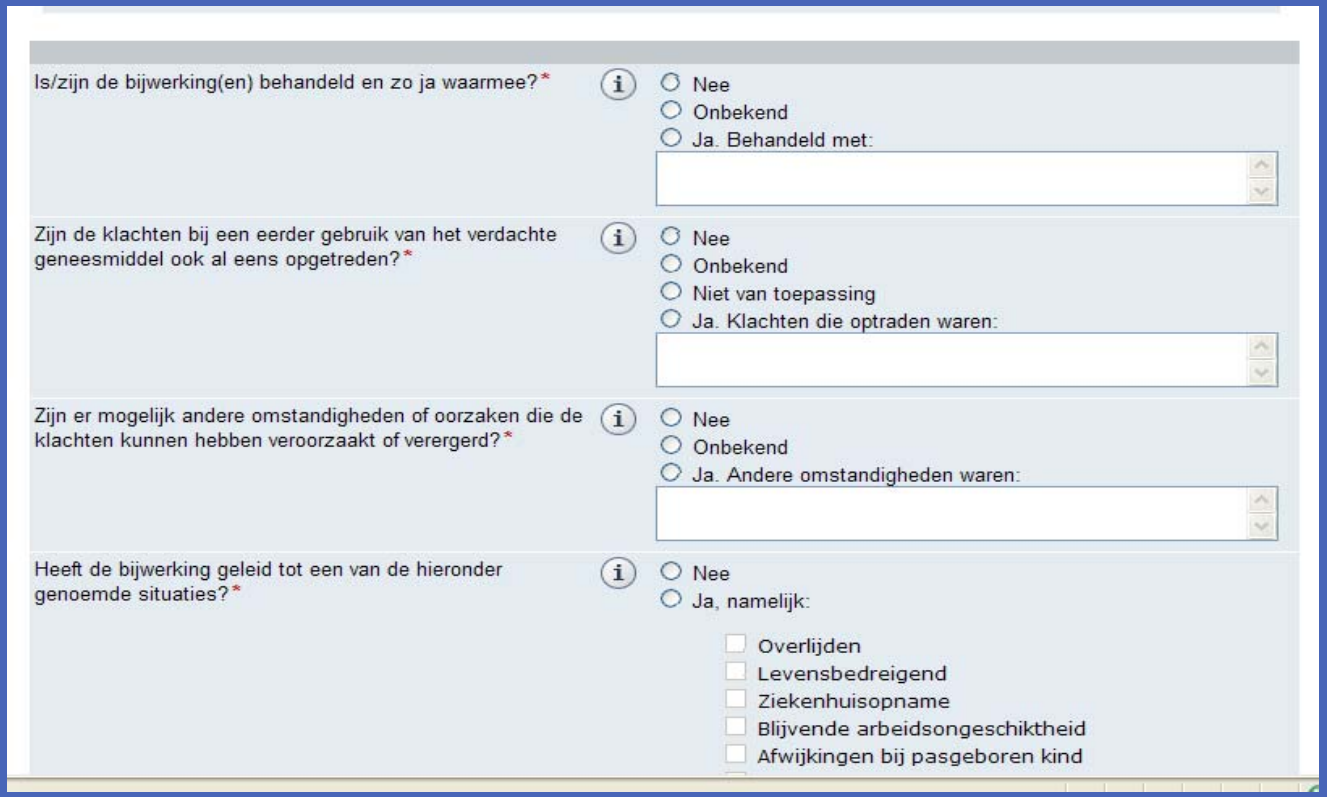
Bijwerking [1]

Vermoedelijke bijwerking*	(i)	
Begindatum bijwerking* *(dag en maand zijn niet verplicht, maar graag zo precies mogelijk invullen)*	(i)	-- dag -- / -- maand -- / -- jaar --
Hoe lang gebruikte u het geneesmiddel voordat de klachten optraden?	(i)	selecteer eenheid
Afloop*	(i)	selecteer afloop...
Waren er nog andere bijwerkingen?		Andere bijwerking +

Direct Patient Reporting

REPORTFORM

PART 2



Is/zijn de bijwerking(en) behandeld en zo ja waarmee?*
- Nee
- Onbekend
- Ja. Behandeld met:

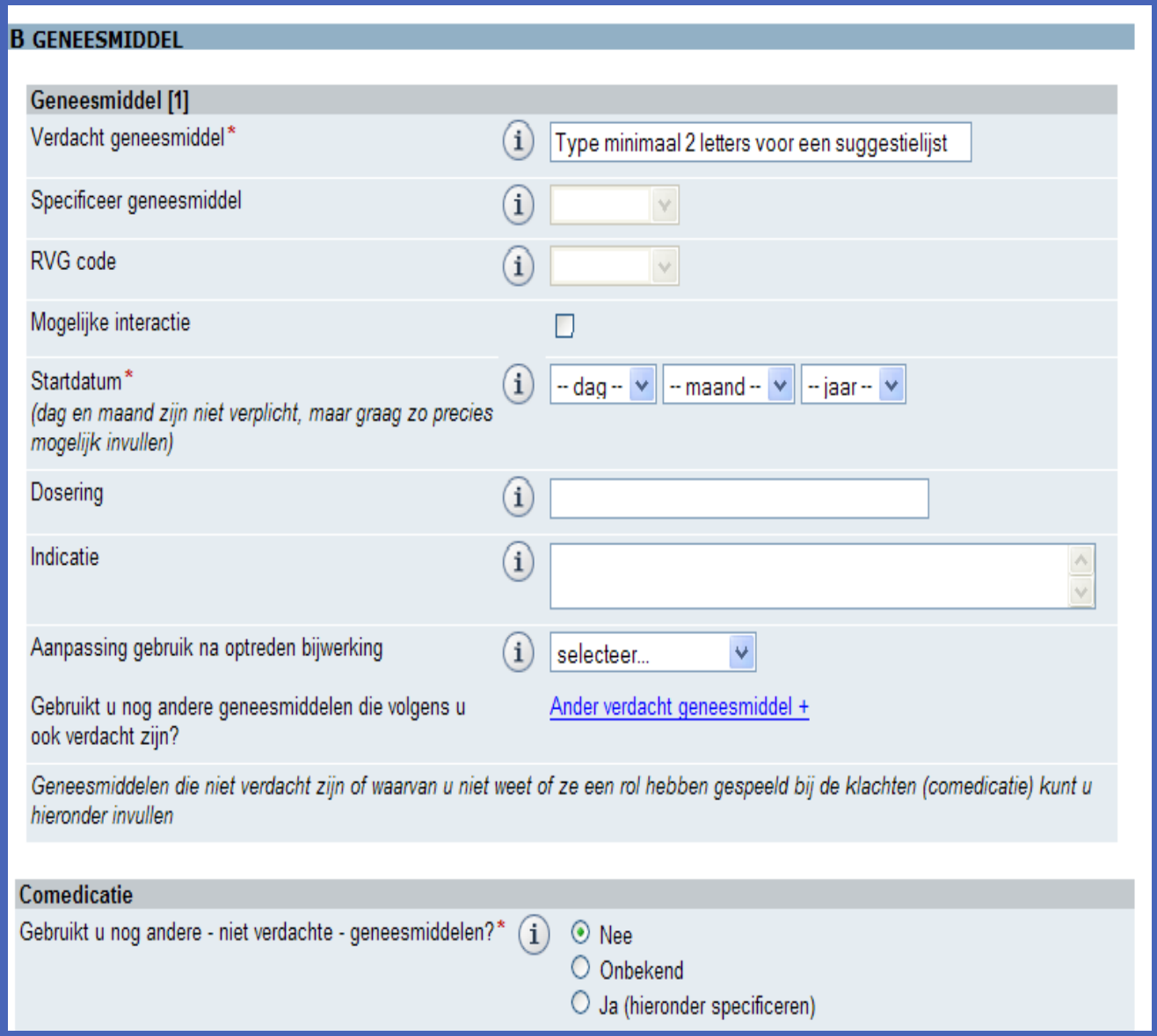
Zijn de klachten bij een eerder gebruik van het verdachte geneesmiddel ook al eens opgetreden?*
- Nee
- Onbekend
- Niet van toepassing
- Ja. Klachten die optraden waren:

Zijn er mogelijk andere omstandigheden of oorzaken die de klachten kunnen hebben veroorzaakt of verergerd?*
- Nee
- Onbekend
- Ja. Andere omstandigheden waren:

Heeft de bijwerking geleid tot een van de hieronder genoemde situaties?*
- Nee
- Ja, namelijk:
  - Overlijden
  - Levensbedreigend
  - Ziekenhuisopname
  - Blijvende arbeidsongeschiktheid
  - Afwijkingen bij pasgeboren kind

REPORTFORM

PART 3



B GENEESMIDDEL

Geneesmiddel [1]

Verdacht geneesmiddel*
Type minimaal 2 letters voor een suggestielijst

Specificeer geneesmiddel

RVG code

Mogelijke interactie

Startdatum*
(dag en maand zijn niet verplicht, maar graag zo precies mogelijk invullen)
-- dag -- | -- maand -- | -- jaar --

Dosering

Indicatie

Aanpassing gebruik na optreden bijwerking
selecteer...

Gebruikt u nog andere geneesmiddelen die volgens u ook verdacht zijn?
Ander verdacht geneesmiddel +

Geneesmiddelen die niet verdacht zijn of waarvan u niet weet of ze een rol hebben gespeeld bij de klachten (comedicatie) kunt u hieronder invullen

Comedicatie

Gebruikt u nog andere - niet verdachte - geneesmiddelen?*
- Nee
- Onbekend
- Ja (hieronder specificeren)

Direct Patient Reporting

REPORTFORM

PART 4

D GEGEVENS VAN DE MELDER

Beroep/specialisme*	○ Huisarts ○ Apotheker ○ Ziekenhuisapotheker ○ Specialist, nl: ____ ○ Overig, nl: ____
Voornaam/voorletters	
Achternaam*	
Naam instelling, afdeling en specialisme*	
Adres	
Postcode	
Plaats	
Telefoonnummer	
e-mail*	

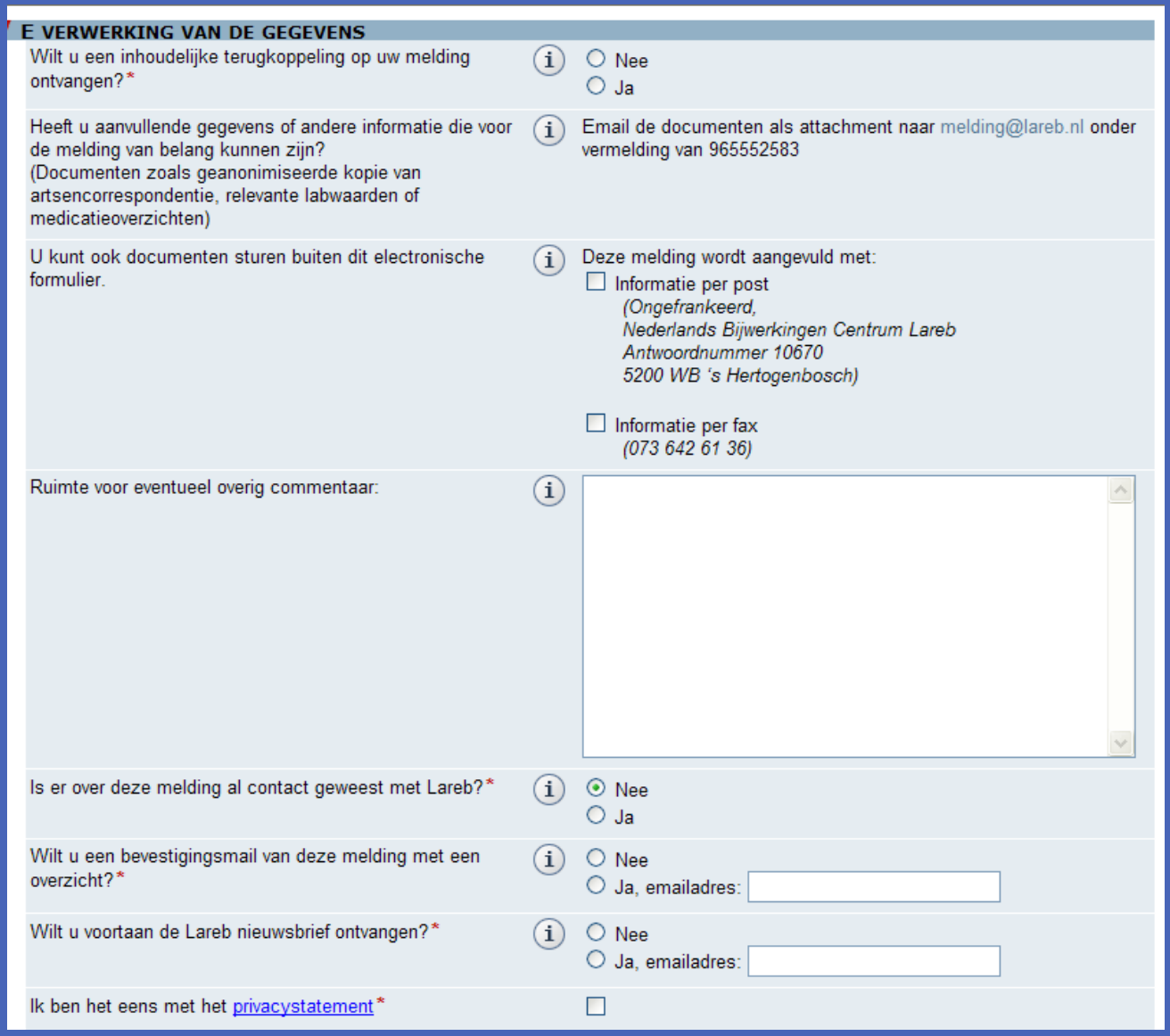
Wanneer u ook namens een andere behandelaar meldt, verzoeken wij u zijn of haar gegevens te vermelden bij het blok "overig commentaar" onder aan dit formulier.

E VERWERKING VAN DE GEGEVENS

Wilt u een inhoudelijke terugkoppeling op uw melding ontvangen?*	○ Nee ○ Ja
Heeft u aanvullende gegevens of andere informatie die voor de melding van belang kunnen zijn? (Documenten zoals geanonimiseerde kopie van artsencorrespondentie, relevante labwaarden of medicatieoverzichten)	Email de documenten als attachment naar melding@lareb.nl onder vermelding van 965552583
U kunt ook documenten sturen buiten dit electronische formulier.	Deze melding wordt aangevuld met: ☐ Informatie per post *(Ongefrankeerd,* *Nederlands Bijwerkingen Centrum Lareb*

REPORTFORM

PART 5



E VERWERKING VAN DE GEGEVENS

Wilt u een inhoudelijke terugkoppeling op uw melding ontvangen?*	i	○ Nee ○ Ja
Heeft u aanvullende gegevens of andere informatie die voor de melding van belang kunnen zijn? (Documenten zoals geanonimiseerde kopie van artsencorrespondentie, relevante labwaarden of medicatieoverzichten)	i	Email de documenten als attachment naar melding@lareb.nl onder vermelding van 965552583
U kunt ook documenten sturen buiten dit electronische formulier.	i	Deze melding wordt aangevuld met: ☐ Informatie per post *(Ongefrankeerd,* *Nederlands Bijwerkingen Centrum Lareb* *Antwoordnummer 10670* *5200 WB 's Hertogenbosch)* ☐ Informatie per fax *(073 642 61 36)*
Ruimte voor eventueel overig commentaar:	i	
Is er over deze melding al contact geweest met Lareb?*	i	◉ Nee ○ Ja
Wilt u een bevestigingsmail van deze melding met een overzicht?*	i	○ Nee ○ Ja, emailadres:
Wilt u voortaan de Lareb nieuwsbrief ontvangen?*	i	○ Nee ○ Ja, emailadres:
Ik ben het eens met het privacystatement*		☐

FEEDBACK

Lareb

Nederlands Bijwerkingen Centrum
Netherlands Pharmacovigilance Centre

A+ A A-

New information | Way of working | Knowledge | About Lareb | Contact | Nederlands

- **Overview signals**
- Quarterly Reports
- Search drug
- Search ADR
- Publications
- Presentations
- ADRs general
- History
- Links

Overview Signals

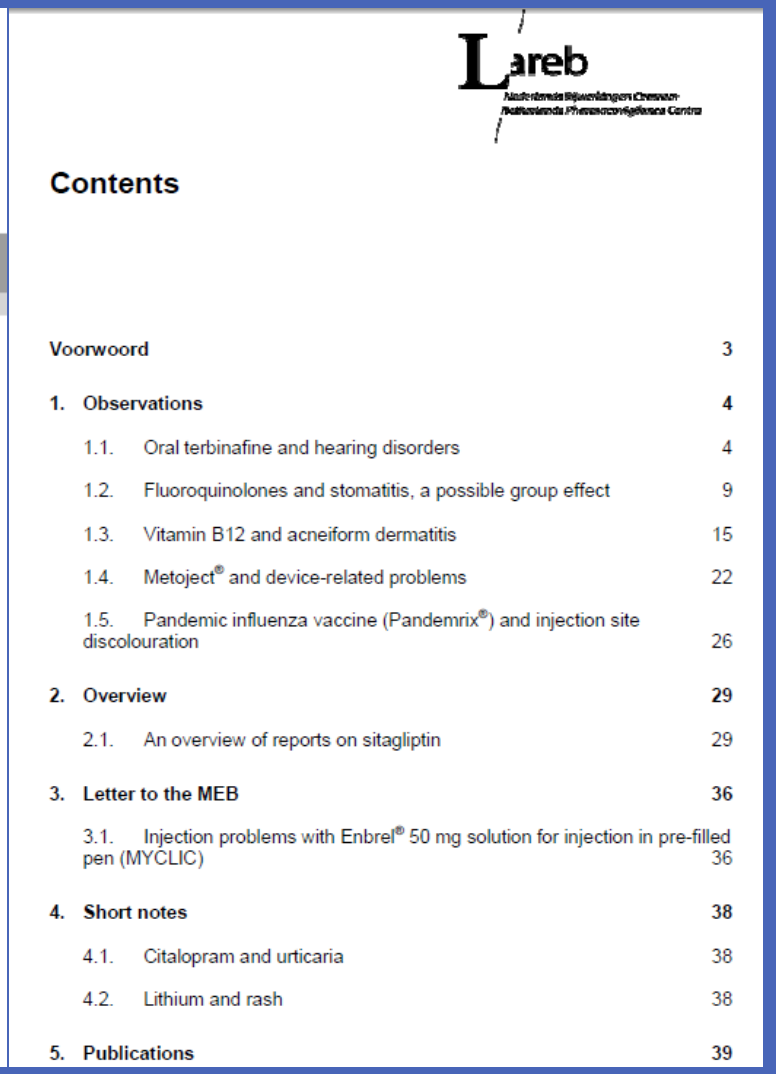
On a regular basis Lareb informs the Dutch Medicines Evaluation Board about possible signals. Some of these messages are in Dutch only. Please use the 'search function' for easy access to these signals

Type a word to filter the results:

Title	File
A combination of metoclopramide and selective serotonin reuptake inhibitors: additional extrapyramidal effects?	
ACE-inhibitors and flushing	
Ace-inhibitors and hallucinations	
ACE-inhibitors and nightmares or abnormal dreaming	
Acetylcysteine and diarrhoea	
Adalimumab and pustular psoriasis	
Alendronate sodium and uveitis	
Alpha-1 blocking agents and liver disorders	
Amlodipine en fotosensitiviteit	
Amoxiciline-clavulaanzuur (Augmentin®) en leverfunctiestoornissen	
An overview of reports concerning implantation complications and unintended pregnancy on etonogestrel	
An overview of reports on montelukast	
An overview of reports on sirolimus	
An overview of reports on tiotropium bromide	
Anaphylactic reaction on sulphur hexafluoride	

FEEDBACK


Lareb
New information
Way of working
Knowledge
About Lareb
Contact
Overview signals
Quarterly Reports
Search drug
Search ADR
Publications
Presentations
ADRs general
History
On this page, the quarterly reports the Netherlands Pharmacovigilance Centre sents to the Dutch Medicines Evaluation Board are shown:
Lareb Quarterly Report 2011-1
Lareb Quarterly Report 2010-4
Lareb Quarterly Report 2010-3
Lareb Quarterly Report 2010-2
Lareb Quarterly Report 2010-1
Lareb Quarterly Report 2009-4
Lareb Quarterly Report 2009-3


Lareb
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1. Observations 4
1.1. Oral terbinafine and hearing disorders 4
1.2. Fluoroquinolones and stomatitis, a possible group effect 9
1.3. Vitamin B12 and acneiform dermatitis 15
1.4. Metoject® and device-related problems 22
1.5. Pandemic influenza vaccine (Pandemrix®) and injection site discolouration 26
2. Overview 29
2.1. An overview of reports on sitagliptin 29
3. Letter to the MEB 36
3.1. Injection problems with Enbrel® 50 mg solution for injection in pre-filled pen (MYCLIC) 36
4. Short notes 38
4.1. Citalopram and urticaria 38
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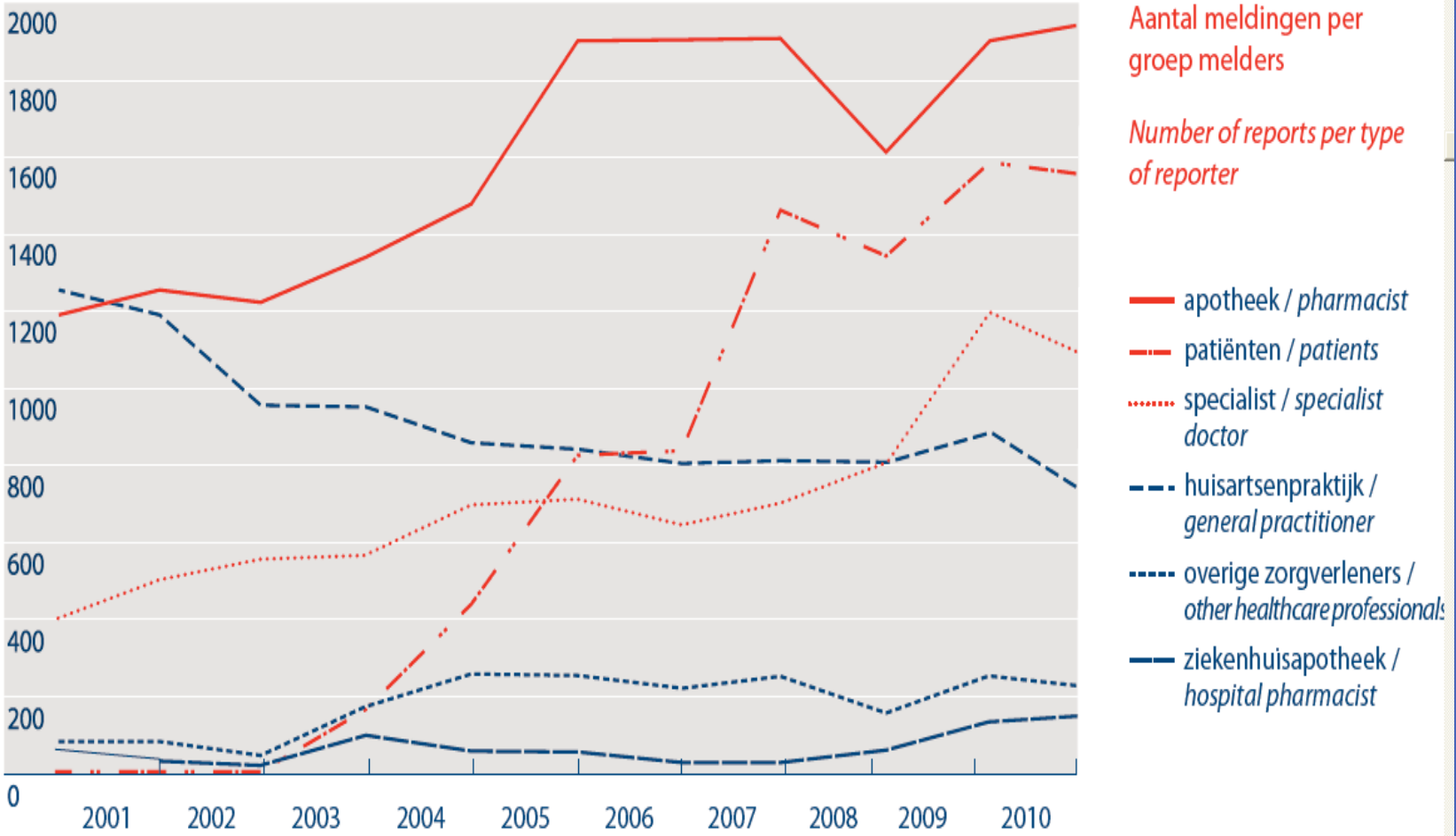
5. Publications 39

FACTS & FIGURES

Aantal meldingen per melder over de afgelopen jaren



FACTS & FIGURES

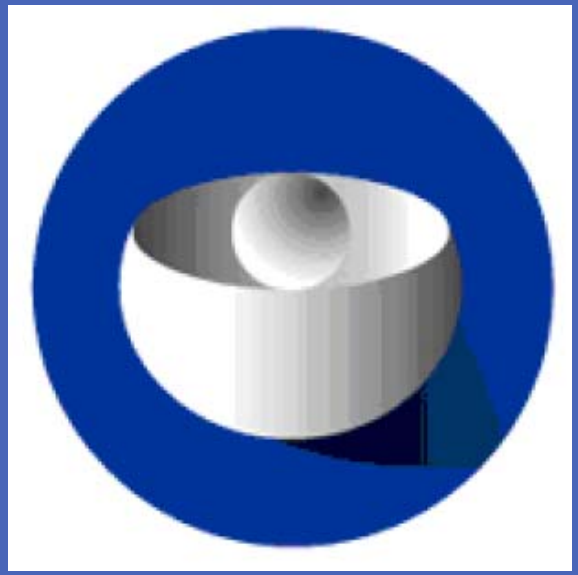
Table 1. ADR reports that contributed to signals from patients and other sources of the reports per year

Quarterly reports per year %, *N*	Patient	General practitioner	Pharmacist	Hospital pharmacist	Specialist	Other healthcare professional*	Pharmaceutical company	*Total*
2003	(0)	15% (17)	20% (22)	1% (1)	21% (23)	2% (2)	41% (46)	*111*
2004	1% (1)	31% (50)	39% (63)	2% (3)	14% (23)	2% (3)	12% (19)	*162*
2005	5% (8)	38% (63)	31% (51)	2% (4)	14% (23)	4% (6)	7% (11)	*166*
2006	5% (8)	28% (42)	32% (49)	1% (1)	25% (38)	1% (2)	7% (11)	*151*
2007	12% (19)	18% (28)	38% (60)	1% (1)	20% (32)	2% (3)	9% (15)	*158*
2008	9% (31)	24% (86)	33% (119)	1% (3)	15% (56)	1% (4)	17% (63)	*362*
Total	*6% (67)*	*26% (286)*	*33% (364)*	*1% (13)*	*18% (195)*	*2% (20)*	*15% (165)*	*1110*

*Other Healthcare Professionals include physicians without specialisation, physicians with their own pharmacy, National Immunisation Programme reports and reports from groups like nurse practitioners etc.

Hunsel Van et. Al. Pharmacoepidemiology and Drug Safety 2011; 20: 286–291

Thanks for your attention



FACTS & FIGURES

Table 2. Trigger reports of the cases grouped by patient and other (healthcare professional and pharmaceutical industry) reporters per year

Year	Number of patient 'trigger reports', (%)	Number of 'trigger reports' by other reporters, (%)	Total number of 'trigger reports'
2003	0 (0%)	14 (100%)	14
2004	0 (0%)	16 (100%)	16
2005	3 (16%)	16 (84%)	19
2006	3 (14%)	18 (86%)	21
2007	5 (28%)	13 (72%)	18
2008	4 (20%)	16 (80%)	20
Total	*15 (14%)*	*93 (86%)*	*108 (100%)*

Hunsel Van et. Al. Pharmacoepidemiology and Drug Safety 2011; 20: 286–291

Organisation

Marketing Authorization Holders

Annual reports and more

Privacystatement

Disclaimer

Organisation

When founded in 1991 Lareb was a reference for the 'Landelijke Registratie en Evaluatie van Bijwerkingen' (National Registration and Evaluation of Adverse drug reactions). Since 2002 we have gone by the name of Netherlands Pharmacovigilance Centre Lareb. Lareb is a network organisation and has close contacts both on a national and international basis. Presently Lareb consists of 30 employees. In addition we have a board and scientific advisory council.

After the thalidomide (Softenon/Distaval) affair in the 1960s, national and international legislation was introduced for the registration and monitoring of adverse drug reactions. At the time of marketing not all adverse drug reactions are known. Clinical research is usually limited to relatively small groups of selected patients. Once these medicines are prescribed to large numbers of patients in daily practice, relatively rare adverse drug reactions, interactions with other medicines or specific user-group effects may come to light.
Lareb collects and analyses reports of suspected adverse drug reactions reported by health care professionals, patients and marketing authorization holders. Lareb informs both government and health professionals about important new signals. Moreover, Lareb tries to increase health professionals' involvement in pharmacovigilance, so they will be motivated to report adverse drug reactions in daily practice. Each year Lareb receives about 6000 reports of adverse drug reactions. In 20% of these reports, a serious adverse drug reaction is reported. Approximately 30 articles are published annually in national and international journals.

Lareb as organization
In the Netherlands, post-marketing surveillance is a responsibility of the Medicines Evaluation Board (MEB) and the Netherlands Pharmacovigilance Centre Lareb. The MEB is responsible for the information originating from the Marketing Authorization Holders (PSUR's, Risk Management Plans, etc). The Netherlands Pharmacovigilance