

Highlights 2016

A collection of white and orange tablets and two medicine bottles on a light blue surface. The tablets are scattered in the foreground, with some white and some orange. The bottles are in the background, slightly out of focus. The overall scene is brightly lit with a soft blue glow.

netherlands
pharmacovigilance
centre **lareb**

Reports

The Netherlands Pharmacovigilance Centre Lareb identifies risks associated with the use of medicines in daily practice and is the knowledge centre for adverse drug reactions (ADRs). Lareb collects 20.000 to 25.000 reports of ADRs yearly. Since 2010 the number of reports more than doubled. Analysis of reports lead to signals about ADRs.

**Reported ADRs by HCPs
and patients**

9.702

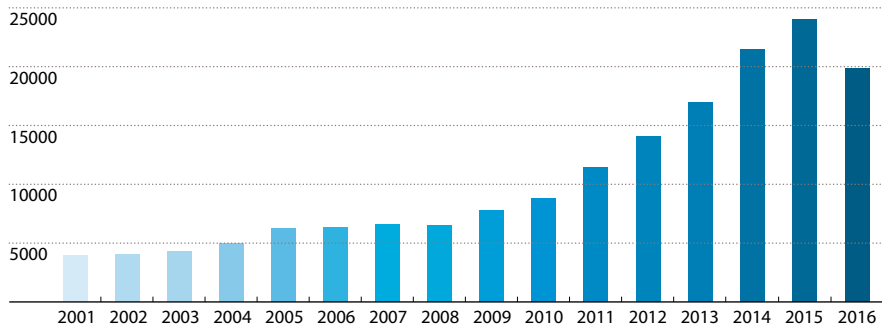


**Reported AEFIs by HCPs
and patients**

1.959



Number of reports 2001-2016



Reporters

Percentage of reports per group in 2016

A Patients	55%
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B Medical specialists	15%
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C Pharmacists	12%
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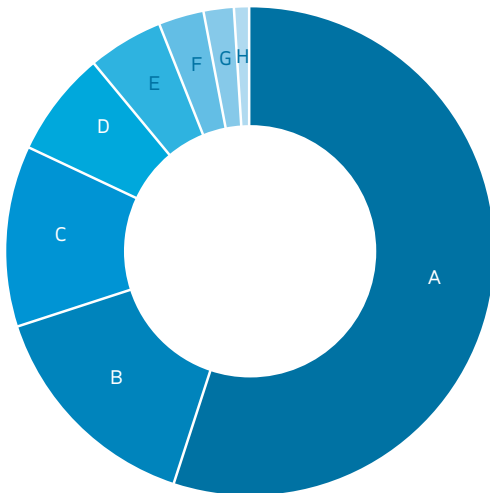
D General practitioners	7%
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E Nurses	5%
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F Public health specialists	3%
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G Other HCPs	2%
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H Hospital pharmacists	1%
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Lareb Intensive Monitoring

Lareb Intensive Monitoring is a method in which patients fill in several online questionnaires about their experiences with medicines or vaccines. This method provides early insights in characteristics of adverse drug reactions (ADRs). For example: the course of ADRs, risk factors, treatment, and the impact ADRs can have on the patient's daily life. This is important information for healthcare professionals and patients to be able to make informed decisions about the use of certain medicines. In addition, it provides information on what to expect, or what actions to take, once a patient experiences an ADR.

In 2016 2.560 users of 19 drugs were monitored by LIM, such as the antidiabetic drugs and new oral anticoagulants. The number of new inclusions was 527. Also 611 patients were monitored by LIM following influenza vaccination.

Monitored by LIM

Drugs

19



Participants

2.560



Vaccine

1



Participants

611



Signals

Based on these analyses, 30 signals were detected.

1. Statins and diplopia

2. Paroxetine and gynaecomastia

3. Vaginal estriol and influenza-like symptoms

4. Minocycline and erythema nodosum

5. Overview reports Midalgan warm® and Midalgan extra warm®

6. Sulfamethoxazole with trimethoprim and Tooth and tongue discolouration

7. Substitutie van flecaïnide

8. Doxycycline and fixed drug eruptions

9. Annual review 2015 reports under the Commodity Law

10. Methylphenidate and priapism

11. Overview anti-epileptic drugs and lack of efficacy after drug substitution

12. Update overview new oral anti-diabetic drugs

13. Flucloxacillin and AGEF

14. Simvastatin 20 mg Accord and remarkable taste

15. Dermal corticosteroids and withdrawal symptoms

16. Idelasinib and leukocytosis

17. Clioquinol overview—an update

18. DOAC overview

19. Vitamin B6 and neuropathy – an update

20. Reports after substitution generic omeprazol to Omecat®

21. MMRvaxPRO and persistent crying

22. Mebeverine and amphetamine drug test positive

23. Ferrofumarate and tooth discolouration

24. Desoximethasone and bloodglucose increased

25. Azathioprine and chromaturia

26. Overview of reports received after substitution of levothyroxine due to Thyrax Duotab out-of-stock

27. Insulin aspart and Medical Device complication

28. Decreased effectivity associated with the revised formulation of the salbutamol aerosol from Sandoz®-- an update of the reports

29. Enzalutamide capsules and swallowing difficulties

30. Desloratadine and behavioural changes- an update

Knowledge centre

(Inter)national publications

75



Publications lay press

55



TV/Radio broadcasts

6



Newsletter subscribers

10.112



Lareb was regularly in the news. For example about long lasting adverse drug reactions following immunization with Cervarix®, vitamin B6 causing peripheral neuropathy and decreased efficacy associated with the revised formulation of salbutamol aerosol.

Information requests

1.822



Lectures

45



Presentations

31



Congres booths

16



Teratology Information Service (TIS)

TIS is Lareb's knowledge centre for medication use during pregnancy and lactation.

Telephone consults
by TIS

2.200



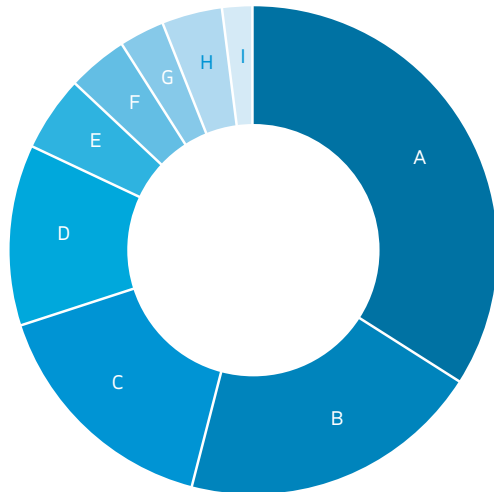
Web service
users

69.455



Who called TIS

A Midwives	34%
B Gynaecologists	20%
C Pharmacists	16%
D General practitioners	12%
E Other physicians	5%
F Public	4%
G Psychiatrics	3%
H Other HCPs	4%
I Other	2%



Goudsbloemvallei 7
5237 MH 's-Hertogenbosch
The Netherlands
+31 73 64 69 700
info@lareb.nl
www.lareb.nl