Highlights 2017

netherlands
pharmacovigilance
centrelareb

Reports

The Netherlands Pharmacovigilance Centre Lareb identifies risks associated with the use of medicines in daily practice and is the knowledge centre for adverse dugs reactions (ADRs) and adverse events following immunisation (AEFI). Lareb collects 20.000 to 25.000 reports of ADRs yearly. Since 2010 the number of reports by patients, Healthcare professionals (HCP) and industry has more than doubled. Analysis of the ADR reports led to 29 signals in 2017.

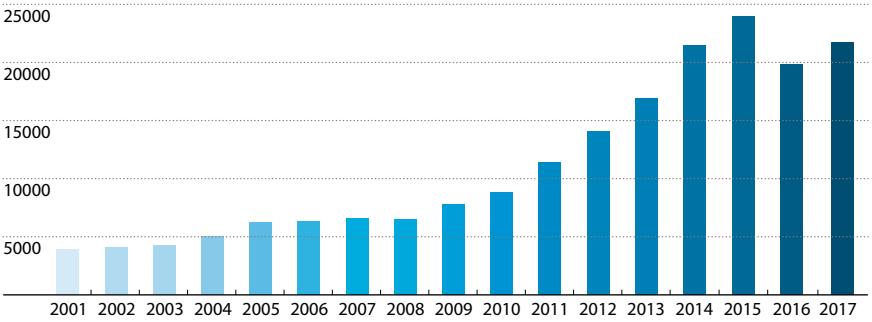
Reported ADRs by HCPs and patients

10.992

Reported AEFIs by HCPs and patients

1.785

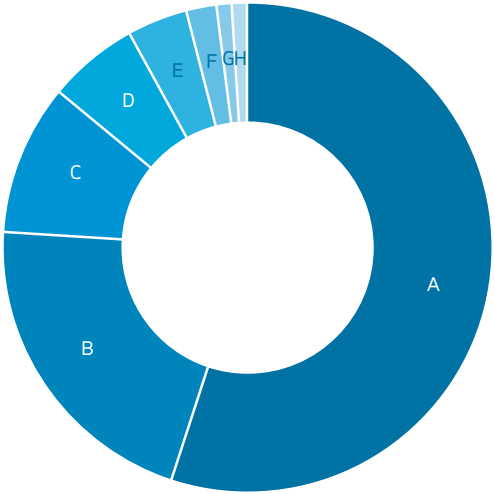
Numbers of reports by patients, HCP and industry 2001-2017



Reporters

Percentage of reports per group in 2017

A	Patients	55%
B	Medical specialists	21%
C	Pharmacists	10%
D	General practitioners	6%
E	Nurses	4%
F	Public health specialists	2%
G	Other Healthcare professionals	1%
H	Hospital pharmacists	1%



Lareb Intensive Monitoring

In addition to the spontaneous reporting system, Lareb also runs an intensive monitoring program called Lareb Intensive Monitoring (LIM). This program compromises observational prospective cohort studies in which real world data is actively collected in a population with one common characteristic (e.g. similar medication use or disease). The goal of LIM is to monitor the use and safety of drugs on short term. Thereby providing actionable knowledge resulting in improvement of pharmacotherapy and management of expectations regarding adverse drug reactions for both HCPs and patients. Patients register online and receive web-based questionnaires on predefined moments in time. Information collected concerns patient characteristics, actual drug use, possible adverse effects and related aspects like course, treatment, burden and risk factors.

In 2017, the LIM study on new oral anticoagulants was continued. Like previous years, the seasonal influenza vaccination has been monitored. The LIM infrastructure has also been deployed for the Monitor Biologicals that started off in 2017. In total 1431 new patients have been included in these LIM-studies.

Monitored by LIM

Studies

4

New participants

1.431

Signals

Based on the analyses of ADR reports, 29 signals were detected.

1. Metabole acidose met hoge aniongap (HAGMA) door interactie tussen paracetamol en flucloxacilline - Update cases
2. Salmeterol with fluticasone and lack of efficacy after drug substitution
3. Dexamfetamine and Raynaud
4. Overview of completed suicides with varenicline
5. Mesalazine and photosensitivity
6. Update Overview on Cervarix®
7. Dalteparine, nadroprine, enoxoparine and headache
8. Midalgan® en buikpijn
9. Overview on direct anticoagulants -update 2017
10. Omnipod Ysomed Pump and application site reactions
11. Off-label use of methylphenidate in adults
12. Dasatinib and nephrotic syndrome
13. Overview on reports of drug substitution
14. Abdominal pain, chest pain and headache while using noscapine
15. Fyto-estrogens with hop and soy and post-menopausal bleeding
16. Tabex® and psychosis
17. Calcipotriol betamethason foam and sticky hair
18. Paroxetine and bruxism
19. Methylphenidate and lack of efficacy after drug substitution
20. DOACs and cholesterol embolism
21. Overview on Red Yeast Rice
22. Jaarrapport 2016: Bijwerkingen na vaccinaties in het kader van het Rijksvaccinatieprogramma
23. Meldingen van bijwerkingen na influenzavaccinaties - Rapportage Influenza seizoen 2016-2017
24. Prevalin direct® neusspray –verwarring naamgeving
25. Salbutamol and hallucinations
26. Decreased international normalised ratio (INR) associated with substitution of acenocoumarol from the manufacturer Sandoz to acenocoumarol from the manufacturer Centrafarm
27. Omeprazole suspension and regurgitated gastric content discoloured
28. Levodopa/carbidopa en verpulverde tabletten
29. Pipamperone and increased appetite and increased weight

Knowledge centre

(Inter)national publications

83

Publications lay press

81

TV/Radio broadcasts

4

Newsletter subscribers

11.864

Lareb appeared regularly in the news. For example about the use of methylphenidate in adults, adverse drug reactions of red yeast rice and the effects on the coagulation time after substitution of acenocoumarol into another brand.

Information requests

1.875

Lectures

50

Presentations

14

Congres booths

10

Teratology Information Service (TIS)

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

Information requests

1.707

pREGnant

With the Dutch Pregnancy Drug Register pREGnant, Lareb aims to get more insight in medication use during pregnancy and breastfeeding and the safety regarding the health of the fetus / infant as the health of the pregnant woman. In 2017, 800 pregnant women were enrolled, whereas the total number of participants in pREGnant was 3264 at the end of 2017. Currently, steps are taken to implement the pREGnant-register on large scale.

New participants

800

Participants in total

3.264

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