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Lareb quarterly newsletter

In this fourth Lareb quarterly e-newsletter we present to you our new signals, abstracts of our publications and other relevant pharmacovigilance news from Lareb. We welcome feedback about this newsletter.

News

Lareb celebrates it's 20-year anniversary

On March 18th, 2011, the Netherlands Pharmacovigilance Centre Lareb celebrated its official 20-year anniversary. Dr. Fred de Koning, pharmacist and founder of Lareb, was awarded the 'Lareb prize' during Lareb's anniversary meeting. The prize was awarded to him in recognition of his contribution to Lareb, pharmacotherapy and the role of the pharmacist.

Dr. June Raine, Chair of the Pharmacovigilance Working Party (EMA) and Director of the Post-Licensing Division at the Medicines and Healthcare Products Regulatory Agency (MHRA) gave a presentation about 'Reports of ADR's as the basis of drug safety' during Lareb's anniversary meeting.

New Signals

This is the information about possible signals from the Netherlands Pharmacovigilance Centre Lareb for the 4th quarter of 2010.

Below you will find a short summary of the signals that Lareb has been working on in the previous period. You will be able to find the entire signals on our website www.lareb.nl, by clicking the link.

Inhaled fluticasone and epistaxis

The association between inhaled fluticasone and epistaxis is supported by the disproportional number of reports both in the Lareb and WHO database, the known effects of inhaled corticosteroids on skin haematoma, and the fact that epistaxis is a known adverse drug reaction for nasal administration of fluticasone. The entire signal can be found [here](#)

Norfloxacin and hypoglycaemia

Hypoglycemia due to some fluoroquinolones is well established in literature and is supported by a plausible mechanism. In addition to the five reports about norfloxacin, Lareb has received reports of hypoglycaemia in association with moxifloxacin (1 report), ciprofloxacin (1 report) and levofloxacin (1 report). The potential to induce hypoglycaemia differs between fluoroquinolones and due to the absence of reports in literature, norfloxacin is likely to be one of the fluoroquinolones with a lesser potential to induce hypoglycaemia. The entire signal can be found [here](#)

Bisphosphonates and depressive reactions

Lareb received 14 reports concerning depressive reactions with the use of alendronate or etidronate. In nine cases there was a positive dechallenge and in one patient also a positive rechallenge. These cases illustrate a possible signal of depressive reactions occurring with alendronate, pamidronate and etidronate. The entire signal can be found [here](#)

Oxaliplatin and laryngospasm

Lareb received four reports of laryngospasm associated with the use of oxaliplatin. Subjective feeling of laryngospasm is described in the SmPC. However, in at least one report there was also intubation and therefore objective evidence for laryngospasm. The entire signal can be found [here](#)

Publications

These are the articles that were recently published in English:

Uterine Perforation with the Levonorgestrel-Releasing Intrauterine Device, Analysis of Reports from Four National Pharmacovigilance Centres (Drug Saf 2011; 34 (1): 83-88)

National pharmacovigilance centres in the Netherlands, New Zealand, Switzerland and Germany did a search on their adverse drug reaction databases for reports of cases of uterine perforation after insertion of a LNG-IUD received between the introduction of the LNG-IUD onto the market in the late 1990s and 15 July 2007. The number of women affected and patient characteristics such as age, parity and breastfeeding status were examined. In addition, the method of detection of the perforation and the time until discovery of the perforation were analysed. The publication can be found [here](#)

Intensive Monitoring of Pregabalin, Results from an Observational, Web-Based, Prospective Cohort Study in the

Netherlands Using Patients as a Source of Information (Drug Saf 2011; 34 (3): 221-231)

The objective of this study was to gain insight into the safety and user profile of pregabalin in daily practice, reported by patients via a web-based intensive monitoring system based at the Netherlands Pharmacovigilance Centre Lareb. The publication can be found [here](#)

Monitoring the safety of influenza A (H1N1) vaccine using web-based intensive Monitoring (Vaccine 29 (2011) 1941-1947)

When adjuvant vaccines against the pandemic influenza A (H1N1) virus became available after an accelerated registration process, safety issues dominated the public debate. As part of the immunization campaign, the Dutch government installed an active monitoring of possible adverse events following immunisation (AEFIs). As part of the monitoring we conducted an anonymous prospective cohort study to identify and quantify the occurrence of AEFIs related to pandemic vaccination among the population immunised in general practice. The publication can be found [here](#)

The proportion of patient reports of suspected ADRs to signal detection in the Netherlands: case-control study (Pharmacoepidemiology and drug safety 2011; 20: 286-291)

This study aimed to determine the contribution of patients' adverse drug reaction (ADR) reports to signals detection, through a study of the signals sent by Lareb to the Dutch Medicines Evaluation Board. The publication can be found [here](#)

If you have any remarks, comments or feedback about this newsletter, please let us know! You can send an email with your feedback to ac.vangrootheest@lareb.nl