its dopaminergic and/or noradrenergic properties. A treatment period can range from seven to nine weeks. Duration of nicotine withdrawal symptoms is reported as three weeks on average, but it may extend beyond 30 days post-cessation of smoking.
Aim: To monitor the safety of bupropion therapy prescribed to English National Health Service patients by General Practitioners (GPs).
Methods: A post-marketing surveillance study using the non-interventional observational cohort technique of Prescription-Event Monitoring. Patients were identified from dispensed prescriptions and outcome data; demographic information and events reported since bupropion was first prescribed, were obtained from questionnaires posted to the GPs who first prescribed the drug. Suspected adverse drug reactions (ADRs), reasons for stopping treatment, outcome of pregnancies and causes of death were also requested. Event data were expressed as incidence densities (IDs)—the number of first reports of an event/1000 patient-weeks of exposure. IDs were compared between weeks one to six and seven to nine of bupropion treatment; and also between weeks one to nine and the thirteen weeks after stopping bupropion therapy.
Results: The cohort consisted of 11,735 patients; the median age of male patients was 47 years (range: 16 to 88) and median age for female patients was also 47 years (range: 16 to 87). The most frequently reported events in weeks one to six of treatment included insomnia (ID 6.1), nausea and/ or vomiting (ID 4.8), dizziness (ID 3.7) and headache and/ or migraine (ID 3.4). These events were also among those reported most frequently as suspected ADRs and as the reason for stopping bupropion. Malaise and/or lassitude (ID 3.2) and abnormal sensation (ID 0.8) featured within the thirty highest ranked events, although did not appear specifically on the manufacturer's data-sheet. Significantly more reports of insomnia, nausea and/or vomiting, dizziness, headache and/ or migraine, malaise and/ or lassitude, depression, dry mouth, sweating, tremor, chest pain and/ or tight chest, urticaria, abdominal pain and abnormal sensation occurred in the first six weeks of treatment compared to weeks seven to nine of treatment. These events also occurred significantly more in weeks 1 to 9 compared to the three months after stopping bupropion therapy; in addition to rash, anxiety, pruritus, constipation and dyspepsia. There were ten events coded as 'convulsion/ epilepsy' occurring during all bupropion treatment periods in the cohort of 11,735 patients (0.09%).
Conclusion: This study identifies the safety profile of bupropion as used in the community. Adverse events were reported that did not appear on the manufacturer's data-sheet. Extensive follow-up analyses (and causality assessment for events) are ongoing. The role of nicotine as a confounding factor must be considered.

P097. HMG CoA Inhibitors and rhinitis

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Introduction: A number of ADR reports associating HMG CoA Inhibitors with rhinitis, some of these with a positive dechallenge, prompted us to investigate this association.
Aim of the study: We investigated the association between HMG CoA Inhibitors and rhinitis in the—dataset of the Netherlands Pharmacovigilance Centre LAREB.
Methods: We calculated reporting odds ratios of rhinitis associated with HMG CoA Inhibitors in the database of the Netherlands Pharmacovigilance Centre and the database of the WHO Collaborating Centre for international Drug Monitoring (the Uppsala Monitoring Centre). We searched the literature for reports of this association and for a putative etiological mechanism.
Results: We found rhinitis to be reported as suspected ADR of all HMG CoA Inhibitors that are currently marketed in the Netherlands, both in the LAREB and in the WHO ADR-databases. Rhinitis was reported to be a (common) ADR in clinical trials with atorvastatin, cerivastatin and simvastatin. In the Netherlands rhinitis is listed in the SPC and package insert as ADR to be expected from pravastatin only.
Conclusion: We found rhinitis to be reported to LAREB as ADR of all HMG CoA Inhibitors but to be mentioned in the package inserts of only one of them. Unfamiliarity with this adverse reaction of HMG CoA Inhibitors carries the risk that this ADR will not be recognised and might be misdiagnosed (and treated) as allergic rhinitis or perennial nonallergic rhinitis.

P098. Boosting of reports of adverse drug reactions in children

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Introduction: In 2001, the Netherlands Pharmacovigilance Centre LAREB celebrated its 10-year anniversary. 'Adverse drug reactions in children' was selected as pharmacovigilance topic to be paid special attention. In paediatrics, off-label and unlicensed prescription of drugs is unavoidable because the benefit-risk ratio of many drugs could not be tested in children before the granting of a marketing authorisation. Even when drugs are approved for use in children, the safety data are incomplete. These circumstances warrant additional efforts to collect ADR data in children after approval.
Aim of the study: Description of methods and results to promote reporting of ADRs in children.
Methods: Pharmacists, general practitioners and paediatricians were informed on the impact of ADR in children