**Aim:** To analyse ADR data and identify areas to focus the Yellow Card strategy to strengthen reporting within the UK.
**Method:** We performed an analysis of spontaneous ADR reports received by the MHRA from 2010 to 2014. All drugs were analysed by active substance using the MHRA's drug dictionary and suspected ADRs were classified using Medical Dictionary for Regulatory affairs (MedDRA).
**Results:** 2014 has seen a 36 % increase in the number of ADR reports received compared to 2010 and a 2 % increase from 2013 to 2014. In 2014, the number of Yellow Card reports received from patients form 22 % of all reports directly received by the MHRA whilst HCP reports account for 46 %.2014 has seen a 12.8 % increase in electronic reporting compared to 2013 and electronic patient reports have increased from 73 % in 2010 to 88 % in 2014 whilst electronic HCP reporting increased from 38 % in 2010 to 79 %. The largest proportion of reports was received from GPs (28 %) and the number of reports from nurses fluctuated during 2010–2014 due to various vaccination campaigns.
**Conclusion:** The data highlights the importance of both regular targeted promotional activities to raise awareness of the Yellow Card Scheme, and making ADR reporting as quick, easy and accessible as possible. Continued engagement with HCPs and patients is key to maintaining the success of schemes such as the YCS as well as effective monitoring and communication of drug safety issues.

## P 061

## A Follow-Up Questionnaire: A Successful Tool to Study Topics Related to Packaging Changes of the Drug Thyrax® in the Netherlands

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**Introduction:** The drug Thyrax® (levothyroxine) is indicated for the treatment of hypothyroidism. In December 2013 the packaging of Thyrax® changed from bottle to blister in the Netherlands. The Marketing Authorization Holder introduced this with a patient flyer. In October 2014 the Netherlands Pharmacovigilance Centre Lareb had received over 80 reports of adverse drug reactions (ADRs) associated with this packaging change. About 50 % of the reports mentioned reactions which match symptoms of hyperthyroidism, like palpitations, hyperhidrosis and jitteriness. The Dutch Medicines Evaluation Board was informed about these findings leading to a Direct Healthcare Professional Communication to inform physicians and pharmacist about a possible dosage increase of levothyroxine after switch from bottles to blisters. In February 2015 various media addressed this issue resulting in about 1800 reports concerning ADRs that occurred after this packaging change. Over 90 % of these reports came from patients.
**Aim:** To study communication regarding the Thyrax® packaging change and its impact on the health care system.
**Method:** An electronic follow-up questionnaire was sent out to all patients who reported ADRs associated with the packaging change.
**Results:** The overall response was 73 %. Only 4 % of the respondents was informed in advance about the packaging change. 74 % of the respondents mentioned they had no concerns about a possible change in effect: "I didn't even think about a possible influence of the packaging on ADRs" and "I had no idea this could affect the therapeutic effect". Most of the patients (47 %) thought of a relation between the packaging change and ADRs after media covered this issue: "It was on the news and on the television show 'Radar' there was a woman who had the same complaints I had". As a result of the ADRs most respondents used extra health care, which included at least one extra visit to the general practitioner (79.1 %), specialist doctor (54.5 %) or pharmacy (57.6 %). 85.3 % of the respondents had extra blood tests to determine thyroid levels.
**Conclusion:** Patients who reported ADRs concerning the Thyrax® packaging change are willing to provide extra information. The questionnaire showed that media attention was necessary for patient to relate their ADRs to the packaging change. For the responders of this questionnaire, the packaging change resulted in an increase in use of health care. Since only patients who experienced ADRs reported to Lareb, this analysis should not be generalized to the Thyrax® packaging change in general. However, it gives an idea of what impact a drug packaging may have.

## P 062

## Seasonal and Geographic Variation In Adverse Event Reporting

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**Introduction:** A number of illnesses demonstrate seasonal variations. Pharmacovigilance is unique among public-health surveillance systems in terms of the clinical and quantitative variety of medical illnesses under surveillance.
**Aim:** Using a large health-authority drug-safety database comprised of spontaneously reported adverse events (ADEs), we assessed whether a set of illnesses that might be expected to display seasonality in general, did so when the illness was reported as a suspected adverse drug reaction.
**Methodology:** For this preliminary investigation of the seasonality of illnesses reported as ADEs, we studied data from the US FDA Adverse Event Reporting System (FAERs). A convenience sample of AEs was classified into one of three subsets: one containing AEs expected to be associated with warmer and/or sunnier seasons: photosensitivity reaction, heat exhaustion, heat stroke, and sunburn; one containing AEs expected to be associated with colder seasons: hypothermia and Raynaud's phenomenon; and one in which some data/experience suggests seasonality but for which there was no clear expectation/pre-existing rationale for seasonality: anencephaly and interstitial lung disease. We analysed global data as well as geographic strata corresponding to the United States, Japan, and Scandinavia. Geography-stratified analysis was performed to explore for possible interactions between seasonality and geography, and to provide some internal control comparisons. Seasonality was assessed using a statistical procedure based on a physicogeometric setting that leads to a test statistic involving sine and cosine functions. The method is reminiscent of finite Fourier analysis. This procedure can detect sinusoidal and other types of variation.
**Results:** The following AEs displayed statistically significant seasonal reporting patterns either globally and/or in one/more geographic areas: hypothermia, photosensitivity reaction in Japan, heat exhaustion, heat stroke, and interstitial lung disease (annual sinusoidal); photosensitivity