At the forefront of pharmacovigilance

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Welcome to this the first issue of *Regulatory Rapporteur* focused largely on pharmacovigilance.
Last year proved to be an eventful one for those involved in pharmacovigilance. To highlight just a few of the events:

- In December 2007, the European Commission launched a public consultation on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance. This led to the publication, on 10th December 2008, of the pharmaceutical package, entitled 'Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector'. The second legislative proposal of this package 'aims at better protecting patients by strengthening the EU system for the safety monitoring of medicines (pharmacovigilance)' according to the EC.
- The CHMP adopted the Guideline on the use of statistical signal detection methods in the EudraVigilance data analysis system in June 2008, and it came into effect in December 2008.
- In June, the Note for Guidance on the Development Safety Update Report (DSUR) was published (EMEA/ICH/CHMP/30934/2008) for comment (ICH Topic E2F Step 3).
- An update of Volume 9A of 'The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance', was published in September.
- In November, the MHRA's 'Good Pharmacovigilance Practice Guide' ('The Purple Guide') was published.

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In this issue, we have tried to capture a number of these events. In an interview on page 16 with Dr June Raine, Director of Vigilance Risk Management of Medicines at the UK's Medicines and Healthcare products Regulatory Agency, she comments particularly on the new pharma package, published two weeks before our interview was conducted. Also in this issue, Thomas Goedecke, Sabine Brosch and Peter Arlett of the EMEA write about the EU's PV database, EudraVigilance (see page 6). Kevin Woodward begins a review of veterinary pharmacovigilance in the EU on page 25, addressing specifically in this issue the continuing safety assessment of veterinary medicinal products. The second part of this review will be published in our March issue.

Carrie Scott, GPvP operations manager and pharmacovigilance inspector at the MHRA and the agency's project leader for the Purple Guide, describes the background to, and development of, the practice guide on page 21.

Paolo Biffignandi presents a personal perspective on the complexities of pharmacovigilance, while Axel Wenzel reviews medical device vigilance in Europe and in Germany in particular.

With all the ongoing developments in the pharmacovigilance arena, it is perhaps not surprising that a number of TOPRA members have expressed an interest in establishing a Special Interest Group (SPIN) for pharmacovigilance. By the time you read this, the launch meeting of this group will have taken place. The conclusions of the meeting and the objectives and plans of the group will be published in a forthcoming issue of *InTouch* and summarised on the TOPRA website. If you would be interested in joining this group, please email **pharmacovig@topra.org**.