

One Year Post Exclusivity Adverse Event Review: Rofecoxib

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Background Drug Information

- **Drug:** Vioxx[®] (rofecoxib)
- **Therapeutic Category:** nonsteroidal anti-inflammatory (COX-2 inhibitor)
- **Sponsor:** Merck & CO., Inc.
- **Pediatric Indication:** Relief of signs and symptoms of pauciarticular and polyarticular course of JRA in patients ≥ 2 yo and ≥ 10 kg
- **Original Market Approval:** May 20, 1999
- **Pediatric Exclusivity Granted:** February 18, 2004
- **Pediatric Indication Approved:** August 19, 2004
- **Market Withdrawal:** September 30, 2004

Rofecoxib Drug Use and Adverse Event Report Summary

- Of the nearly 20 million prescriptions dispensed in 2003, approximately 220,000 (1.1%) were dispensed for pediatric patients.^{1,2}
- Adverse event reports during the post-exclusivity period (7 months):
 - 9,626 reports of all ages, 1,049 deaths*
 - 19 pediatric reports (16 unduplicated), 3 deaths

¹IMS Health, National Prescription Audit *Plus*TM, Years 2002 – 2004, Data extracted Jan 2005

²IMS Health, National Disease and Therapeutic IndexTM, Years 2002 – 2004, Data extracted May 2005

*includes duplicate reports

Rofecoxib Pediatric AE Report Deaths: Causality Not Determined

- 3 Deaths (all foreign reports):
 - Adolescent with a salt wasting syndrome, died after receiving treatment with rofecoxib for 18 months. Post-mortem: aspiration, pulmonary emphysema, bleeding underneath the pulmonary pleura, and significant enlargement of the heart; no evidence of MI; infection and myocarditis could not be ruled-out.
 - Pre-adolescent with JRA on rofecoxib 25mg died 5 months later, after chest tightness. Other meds: methotrexate, Chinese traditional medicine, and spiruline (herbal).
 - Expected fetal death after an elective abortion. The examination of the fetus did not reveal any pathological findings. Mother was on rofecoxib for an unspecified indication.

Summary: Rofecoxib

- No new concerning unlabeled safety signals identified in pediatric adverse events reported through AERS in the post-exclusivity period.
- This completes the one-year post-exclusivity AE reporting as mandated by BPCA.
- No further monitoring necessary as the drug has been withdrawn from the market.

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