Payers Care about Drug Safety:

Reimbursement with Accountability

Rose Fishman, BScPhm

Christine Malmberg, PharmD

More than one year after Merck Frosst withdrew Vioxx from the market, the credibility of pharmaceutical manufacturers continues to experience intense scrutiny by both regulators and payers. Of note are some of the following observations, gleaned from newspaper and journal articles, testimonials and interviews with healthcare stakeholders:

- In the US, insurers and some states are taking advantage of the backlash against the pharmaceutical industry by trying to move patients to older, generic drugs, arguing that they work just as well as newer, more expensive branded medicines.
- Physicians are writing fewer prescriptions for antidepressants and other drugs whose safety has been challenged, such as hormone replacement therapies for women in menopause.
- A Canadian pharmacy Benefit Manager reported that out of safety concerns, his organization was seriously considering delaying the listing of expensive drugs for six to 12 months.
- Several Canadian insurers told us they regularly monitor FDA and Health Canada websites for drug safety information so that they can inform clients and react quickly if a reimbursed drug's safety is in question.
- There has been much speculation over the impartiality and effectiveness of regulators (FDA and Health Canada) to ensure the safety of drugs and inform the public of potential dangers in a timely and forthright manner.

While regulators are asking that Risk Management Plans (RiskMAPs) be submitted as part of the condition for their approval, payers are asking that post-market surveillance be a condition of listing. Provincial payers, such as the Ontario Drug Benefit Program, want to link outcomes to reimbursement and a representative has stated that, "there is a disconnect between regulatory review standards and standards of evidence for comparative evaluation for funding decisions."[1]

Following the example of Alberta (which added Remicade® and Enbrel® to their drug benefit list in 2003, only after the implementation of a Rheumatoid Arthritis [RA] Registry funded by the industry), Ontario has set in motion plans to implement a similar, long-term observational study of RA drugs listed on the Ontario Drug Benefit Formulary, which are also to be funded by the manufacturer.

"There is a disconnect between regulatory review standards and standards of evidence for comparative evaluation for funding decisions."[1]

In the post-Vioxx era, all healthcare stakeholders are holding drug manufacturers to greater accountability. The lines between regulatory and reimbursement are starting to blur as payers become more outspoken and involved in protecting the costs of the drug plan and the health of drug plan beneficiaries. Their reasons for concern inlcude the following:

There is a disparity between Health Canada review standards and the evidence required for funding decisions. Provincial formulary decision-makers and the Common Drug Review are demanding comparative long-term trials with both clinically relevant efficacy and safety endpoints for formulary listing. Trials with these designs and endpoints are not available or required at the time of Health Canada's review of the drug.

Clinical trial evidence does not reflect safety in real practice. Adverse events not discovered in Phase III trials may only become apparent in clinical practice as drugs are used by more patients and by those with underlying diseases and concomitant drug therapies.

Payers want to protect their clients—drug plan sponsors and beneficiaries. Payers (both public and private) are concerned that their beneficiaries will be exposed to a drug that will cause more harm than benefit. Pharmacy benefit managers, for example, have expressed a sense of duty to provide good therapeutic advice to beneficiaries, to guard employers from liability and to protect the work environment. Some private payers have stated that they feel increasing pressure from employers who retrospectively question the decision to list Vioxx and the costs incurred.

Cost. When a plan member is absent from work because of an adverse event, the cost is especially high due to the wasted drug, but also due to the employee's lost productivity and possible disability.

For pharmaceutical companies, all this demands a rethinking of the traditional market access paradigm. Payers increasingly demand information that goes beyond the budget impact analysis (BIA). They want assurance that the drug is safe today and that its safety will continue to be monitored during the product life cycle.

There is no invariable method for addressing safety-related brand management and market access issues. However, the industry must develop a new set of rules around payer relations and the issue of safety. CPM

To discuss how your company can focus on what payers want in this new era of safety consciousness, contact:
Rose Fishman, 1-800-811-9880, ext. 104, ***rfishman@phase4health.com*** *or*
Christine Malmberg, ext. 125, ***cmalmberg@phase4health.com****.*

References

1. Dr. Judith Glennie, Associate Director, Drug Programs Branch at DIA-3rd Canadian Annual Meeting, Montreal, September 27, 2005.

McKesson Phase 4 Solutions is a division of McKesson Canada that offers strategic consulting, clinical trial services including late phase clinical trials, health economics and outcomes research, product development and marketing and reimbursement management and payer relations to the pharmaceutical industry.