Commentary: Johan Strömquist

Managers ignore pharmacovigilance at their peril

The implementation of Europe's new pharmacovigilance legislation is currently ongoing, creating ripples as each step forward makes the day-to-day effects more tangible. Since July 2012 a new committee at the European Medicines Agency, the Pharmacovigilance Risk Assessment Committee (PRAC), has started to establish itself as a major influence and stakeholder in the system for regulating medicines.

From a strategic perspective the implementation of the new legislation brings with it several critical aspects that the leadership and management of every pharmaceutical company must take into account as it creates plans to develop new pharmaceuticals. In this article I will summarise three of these aspects: accountability, transparency and perpetual development.

Accountability

The new legislation puts increased accountability on the management of companies to ensure that their processes are used in a safe and efficient way. For example, companies are now required to include with their marketing authorisation dossier a risk management plan that is proportionate to the risk of the product. This plan must describe the pharmacovigilance activities that a company has prepared in order to minimise risks.

High profile cases around the world illustrate that no-one in a decision-making position is untouched by these new measures. Demonstrating a robust safety and monitoring system is essential. Failure to do so threatens not only the safety of patients and the company's good reputation and share price, but also the freedom of individual decision makers.

The new law and supporting guidance documents emphasise the central role of the qualified person for pharmacovigilance. This person is appointed by management to oversee compliance with the new legislation and must be fully integrated into management with oversight of all business functions. Only this way can a company be sure that it has control over all of the post-marketing events that may have an impact on the safety of patients.

Transparency

For many years the EMA has been promoting a culture of transparency. This means giving healthcare professionals and the public access to regulatory documents and to the work of the agency's committees. With the coming into force of the pharmacovigilance legislation, transparency has taken on a new meaning: it has become a whip for driving companies into adopting a more risk-based approach and to focus more on patient safety.

The minutes from PRAC meetings are now being made available on the agency's website; their content could easily become a company's worst nightmare. The committee is currently examining products already on the market for evidence of previously undetected safety signals. It is asking probing questions that are subsequently being published on the agency's website within days of the actual meeting.

The PRAC also has been given a mandate, in certain cases, to hold public hearings. It intends to exercise this right in 2013; to date it is unclear under what circumstances the clause would be invoked.

Society, patients and the financial markets are now being given information about medical products that could shape public opinion about the products and ultimately determine their success.

Perpetual development

By introducing the concept of benefit/risk in the pharmacovigilance legislation, the burden of proof for a product's beneficial effects has been extended way beyond the point of initial approval. It seems that the Committee for Medicinal Products for Human Use (CHMP) no longer holds total exclusivity over the evaluation of a treatment's efficacy. Reading the PRAC minutes highlights how the new committee involves itself in this aspect of its remit.

The implication for a company's development strategy is that all initial approvals in effect are conditional – in the broadest sense of the word. The new legislation requires that companies increase the evidence of a drug's benefit/risk over and above what is required for marketing authorisation. This means gathering more data after authorisation about how a medicine works in clinical practice. Broadening the evidence base with patient outcomes data will improve future drug research and help health technology assessment bodies decide whether or not to recommend a new drug for reimbursement. Conversely, a drug's reimbursement status, and indeed its authorisation, could be called into question if its benefit/risk profile changes as a result of the patient outcomes data. The requirement to continually assess benefit/risk will also affect a company's applications for new indications and its decisions on whether or not to apply for over-the-counter status.

In conclusion, the new pharmacovigilance legislation means that managers of pharmaceutical companies will be held responsible for a drug's performance to an even greater extent than before. Indeed, missteps by management could lead to public disclosures by the EMA. The development phase of a product is now explicitly extended beyond the agency's initial opinion and the European Commission's approval of a product, effectively extending it into the marketing phase. Management must ensure that systems are in place to track a product once it is in clinical practice. This will be essential if a product is to *stay* on the market and be assessed for its true value to patients.

This article was written by Johan Strömquist, chief executive officer of the NDA Group, an independent consulting group based in Germany, Sweden and the United Kingdom.