

# PHARMACEUTICAL RISKS IT NEVER RAINS BUT IT POURS

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**How safe are the medicines we take? Given some of the spectacular product recalls undertaken by the pharmaceutical industry in recent years, this is a question increasingly being asked, and not just by consumers. Insurers and reinsurers are also directly affected by pharmaceutical risks, with both the number and size of compensation claims rising significantly. In order to guarantee long-term insurability, manufacturers and insurers need to rethink their coverage of product liability risks and develop a sophisticated system of risk management.**

Recent events in the global pharmaceutical market have moved loss accumulation issues into the spotlight. In their double role as underwriters and participants in the capital markets, insurers are also facing the issue of cross-balance sheet exposure, a problem which has not yet received sufficient attention.

A drug recall not only harms drug manufacturers, but may also impose a considerable financial burden on insurers as a result of risk accumulation, due to the fact that losses in the pharmaceutical sector can affect several insurance policies at the same time. This mainly concerns product liability and D&O. Other policies which

may be affected include clinical trials cover, medical malpractice and recall cover, which is rarely written in this segment, however. If an entire product family presents similar side effects or if a substance is in widespread use, as is the case with generic drugs, a single event may even affect the product liability policies of different manufacturers. Accumulation scenarios involving different lines of business are not very likely to occur in the pharmaceutical sector. Property covers are not correlated with product liability losses at all. Credit insurance would only be triggered when a business becomes insolvent, and thus only presents a weak correlation.

## **Scenario techniques help to assess the consequences of active ingredient accumulation**

A type of accumulation risk typical for the pharmaceutical sector, which may be called “active ingredient accumulation”, occurs with products which belong to the same product family, act in a similar manner, and therefore could produce comparable side effects. Often, one specific drug will stand out from a product family in having much worse side effects than the others. For example, rhabdomyolysis, a medical condition where muscle cells are broken down and the resulting release of proteins

into the blood may ultimately cause kidney failure and death, is a possible side effect of all statins, a widely-used class of drugs for lowering high blood-lipid levels. Cerivastatin, the active ingredient contained in one lipid-lowering product, had particularly serious side effects and had to be taken off the market in 2001. In some cases, due to differences in the way an active ingredient is metabolised in the body, certain patient populations (e.g. specific ethnic groups, children, elderly or health-compromised patients, or patients already receiving other medications) may be more at risk from side effects than others. For example, the package insert of the lipid-lowering drug rosuvastatin had to be changed to include a warning that Asian patients are at increased risk.

In order to control active ingredient accumulation, critical product classes have to be identified, and a close watch has to be kept on the relevant companies in the insurance portfolio. By examining different potential scenarios, active ingredient accumulation losses can be evaluated more accurately, and measures identified to restrict or ration capacity.

### **Accumulation of risks across the balance sheet**

An accumulation hazard that has not yet received much attention involves exposure affecting both sides of the balance sheet, i.e. assets and liabilities. If a listed pharmaceutical company has to take a product off the market due to serious side effects, its share price can be expected to slump. An insurance company with these shares in its

investment portfolio faces a double financial burden, one from the pharmaceutical cover, the other on the investment side. Negative reports about a drug are sufficient to trigger a plunge in share prices. This happened in the summer of 2002, when a study proved for the first time that hormone replacement therapy is associated with increased breast cancer risk. The share price of the company hit hardest by these findings dropped by one-third within a period of ten days, with the biggest losses occurring directly after the study results were published. In general, it can be said that the higher the expected sales volume of a drug, the higher the manufacturer's dependency on the product, and the stronger the reaction expected from consumers, the more share prices will go down. In addition, share prices will be negatively affected by the threat of possible compensation claims, which are difficult to assess initially. This is why pharma analysts are increasingly including product liability risks in their evaluations.

Empirical studies have shown that there is a short-term effect where shares lose 20 to 35% of their value within a period of two to three weeks, and in some cases even up to 50%. On the two-year horizon, losses in share value range between 10 and 20%. In contrast, longer-term corporate bonds have been found to be only slightly vulnerable.

### **Sensitive financial markets**

If a whole class of drugs falls into disrepute – as has happened recently with cox-2 inhibitor painkillers – the

share prices of several companies or even the entire pharmaceutical industry may suffer as a result. And the accumulation risk across the balance sheet is increasing. An example is the recall of rofecoxib in September 2004.

The manufacturer's share price dropped by about one-third, while the shares of companies selling drugs of the same class initially went up as investors seemed to expect patients to switch to competing products. Shortly after, however, discussion about a potential class effect, i.e. the harmfulness of the entire class of drugs, damaged the most important competitor's share prices, too.

### **Integrated approach**

As a consequence, (re)insurers may face financial losses both on the insurance (liabilities) side and on the asset side of the balance sheet, depending on their investment portfolio. Risk accumulation control should therefore not be limited to the underwriting side, but must also

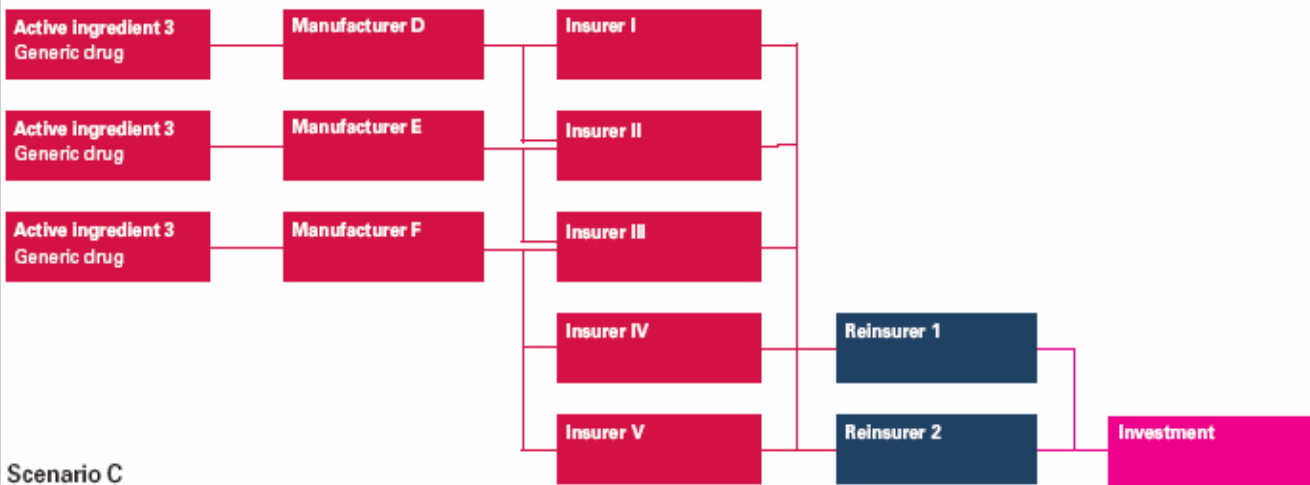
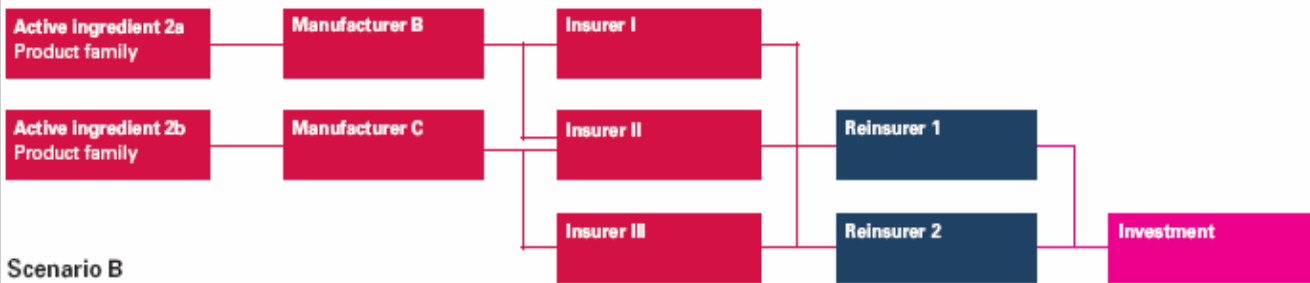
include the investment side, e.g. through a careful selection of shares. Possible correlations should also be taken into account when calculating and allocating risk capital.

### **Outlook: The next recall is on the cards**

In future, the insurance industry will have to tackle large-scale accumulation scenarios, not only in the field of pharmaceuticals. Munich Re is aware of this issue and is actively working on the development of accumulation scenarios to control this hazard without losing sight of business opportunities. Munich Re's Integrated Risk Management initiates portfolio analyses, defines potential early-warning indicators, conducts stress and sensitivity tests and develops tools for an efficient management of accumulation risks impacting different lines of business and both sides of the balance sheet.■

## Active ingredient accumulation – Risk management and accumulation control

Three possible scenarios



**Scenario A:** A drug manufacturer sells a patented ingredient. Several insurance companies participate in the programme. The reinsurer's exposure is limited.

**Scenario B:** A number of manufacturers produce active ingredients which are closely related chemically and belong to the same product family. Several industrial insurers participate in a number of insurance programmes. Overall, the reinsurer provides more capacity.

**Scenario C:** An active ingredient no longer under patent is contained in various "copied" or generic drugs. Several generic drug manufacturers buy insurance cover from various insurance companies. The reinsurer provides even more capacity than in scenario B.

In scenarios B and C, the reinsurance company which assumes the risks ceded by several primary insurers faces high exposure as a result of active ingredient accumulation.

In all three scenarios, there is a potential impact on the reinsurers' investments. While scenario A involves the shares of a single company, however, scenarios B and C may affect the share prices of more than one manufacturer or even a large number of companies.

Source: Munich Re