



# Casualty Risk Trends 2018

## Pharmaceutical industry

While pharmaceutical revenues are traditionally derived from a few products that are heavily marketed, decreasing R&D productivity together with pricing and reimbursement hurdles are driving change in the industry. The emergence of novel and advanced therapies is also creating new opportunities. Economic expansion and increasing affluence in the emerging markets are other factors driving growth in both prescription and over-the-counter drug markets.

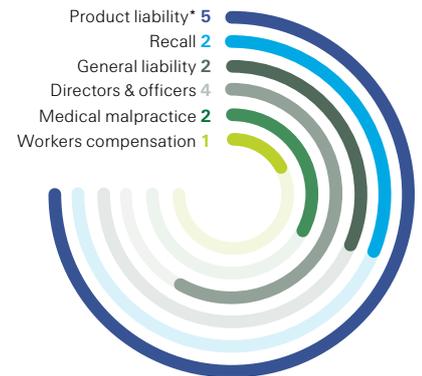


## Trend

## Casualty relevance

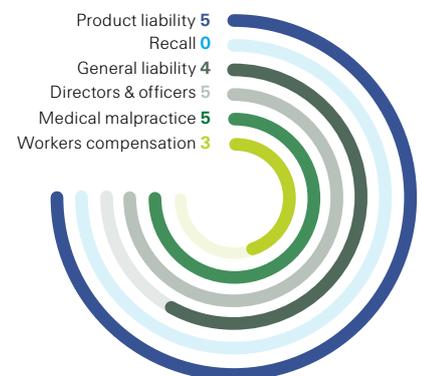
### 1 • Biosimilars

Biosimilars are biological products that bear a high similarity to a reference-approved biological product. Despite some open questions about their labeling, the FDA's approval of the first biosimilar in 2015 has led to an increasing number of biosimilars embarking on the path to approval in the US. Although there are no clinically meaningful differences in the safety and effectiveness of biosimilars compared with their reference products, they are not identical. This can give rise to unexpected safety issues in patients treated with biosimilars (either naive patients or those switching from the original product to the biosimilar). This in turn can generate product liability-related claims on a failure-to-warn basis.



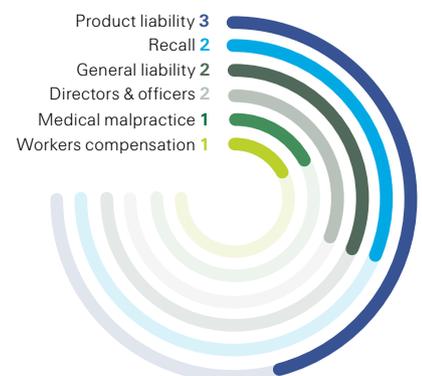
### 2 • Opioid misuse in the US

In 2017, approximately 49 000 deaths were attributed to opioid-related overdoses in the US – this translates into 134 opioid-related deaths each day. Hundreds of US state attorneys general, counties, townships, municipalities, cities, Native American tribes and individuals have filed federal and state civil suits against the manufacturers (pharmaceutical companies), distributors and retailers (pharmacies) for allegedly – by fraudulent or negligent means – falsely and deceptively advertising opioids and their risks, mismanaging their distribution and dispensing practices. Lawsuits have also been filed against doctors for allegedly negligent opioid prescription, failure to monitor addiction development and even for contributing to diverting opioids to the black market.



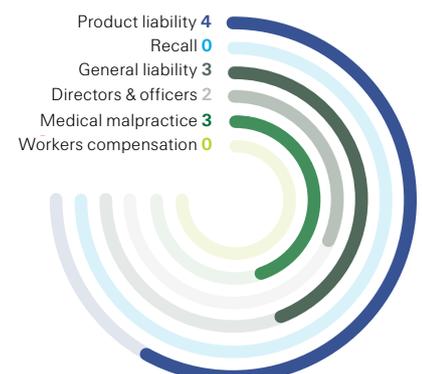
### 3 • New markets

Economic expansion, increased affluence and regulatory reforms in Asia and other emerging markets offer new business opportunities for pharmaceutical companies. For example, last year China launched a reform aimed at optimising the evaluation and approval of drugs and medical devices. As new drugs become available in these regions, the number of patients treated will continue to rise, while claims could take on unexpected developments. Grounds for litigation could include the failure to warn certain ethnic groups of specific responses to medication, unknown interactions with concomitant therapies (eg traditional Chinese medicine), or differences in the cultural aspects of patient compliance (self-over medicating). Local regulatory authorities may also develop alternative views on safety information requirements for product labels.



### 4 • Advanced cell immunotherapies, CAR-T

CAR-T cell therapy is a novel biologic therapy using genetically engineered cells with new properties to target cancer cells. The FDA approved the first CAR-T based treatment in August 2017, and so far, this type of therapy has been indicated for liquid tumors, namely B-cell acute lymphoblastic leukemia. While it represents a major breakthrough in cancer treatment, a number of expected and unexpected toxicities of varied severity have been identified, such as cytokine release syndrome, neurological toxicity or anaphylaxis. These toxicities are mainly linked to the fact that cells are removed from the patients and engineered in vitro before being reinjected into the patient. The long-term effects of CAR-T cells are also not known, as this is a relatively new type of therapy.



\* Product liability in the pharmaceutical industry is inherently linked to bodily injury

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## What can insureds do to minimise these risks?

- The original product should have a well-established safety profile against which to benchmark the biosimilar.
- Ensure extensive testing of the biosimilar in the clinical and manufacturing settings.
- Minimise changes in manufacturing processes, as very small variations can lead to clinically meaningful changes.

## What is important to bear in mind when insuring these risks?

- Check the adequacy of the manufacturing set-up of biologics (in-house or outsourced) and the robustness of overall quality systems.
- Consider that product exposure depends on product sales (market share) and geographical penetration.
- Assess the insured's pharmaceutical value chain, as liability may be influenced by development/manufacturing/marketing partnerships.

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- Closely monitor sales trends across regions and population groups.
  - Rapidly introduce regulatory changes related to warnings of addictive potential and prescription and distribution practices.
  - Improve controls to prevent their diversion to illegitimate channels.

- Properly assess opioid exposure of the account(s) under consideration (ie portfolio of products; role(s) along the supply chain; accumulation potential).
- Remain vigilant with regard to ongoing litigation in the US and potential developments in other regions. Consider applying underwriting risk mitigation measures.
- Consider additional lines of business that could be potentially affected, such as medical malpractice and life & health insurance.

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- Establish suitable marketing and post-marketing support teams to ensure regulatory compliance and react promptly to regulatory developments.
  - Alternatively, do this by joining forces with local organisations.

- Take into consideration that exposure to medicines (patients treated) depends on market and consumer trends in the regions in question.
- Bear in mind that the use of medication by individuals with different genetic backgrounds (ie ethnic groups) can lead to unexpected adverse reactions.
- Monitor regulatory changes and litigation trends closely as markets develop.

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- Critically monitor patient data for acute and long-term adverse events as it becomes available.
  - Adapt to the evolving regulatory environment as regulators develop specific guidelines.

- Take into account that liability drivers may be associated with the aim of therapy (lifestyle vs life-saving) or the emergence of unexpected long-term effects.
  - Novel and advanced therapies are generally subject to customised use on a limited number of patients, thereby making them less attractive targets for mass litigation.
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## **Impressum**

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