

International Product Liability Review

Issue 62

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About our Product Litigation and Compliance Practice

Hogan Lovells has the leading international product liability practice covering all aspects of product liability, compliance and mass torts. We focus on acting for clients around the world covering all products sectors including food and beverages, pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, sporting goods, aircraft and machinery. Hogan Lovells' product liability and product safety lawyers are supported by a dedicated Science Unit and Project Management Unit.

If you would like more information about Hogan Lovells product litigation and compliance practice, please visit our website at www.hoganlovells.com or contact the Product Liability Group Leader, Rod Freeman, at rod.freeman@hoganlovells.com or any of the lawyers listed on the back page of this publication.

ABOUT INTERNATIONAL PRODUCT LIABILITY REVIEW

In December 2000, Lovells (as it then was) launched its quarterly *European Product Liability Review*, the only regular publication dedicated to reporting on product liability and product safety developments in Europe for international product suppliers, and others interested in international product issues. Over the next ten years, this unique publication featured hundreds of articles, from authors across our network, covering issues in Europe and, increasingly, further afield. Reflecting the growing globalisation of product risks, and following the creation of Hogan Lovells through the combination of Lovells with Hogan & Hartson in May 2010, the publication was renamed *International Product Liability Review* in March 2011.

Hogan Lovells *International Product Liability Review* continues to be the only regular publication dedicated to reporting on global developments in product litigation and product regulation. It is distributed worldwide free of charge to our clients and others interested in international product issues. If you would like additional copies of this publication, please return the form enclosed with this edition, or contact a member of the editorial team by e-mail:

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Meet the team

We are pleased to introduce two of the authors who have contributed to this edition of *International Product Liability Review*: Cécile Burgess (London) and Charles-Henri Caron (Paris).



CÉCILE BURGESS

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As a dual qualified English and French lawyer, Cécile Burgess focuses her practice in Hogan Lovells' London office on product liability and compliance. Cécile has experience of acting on a wide variety of disputes, including both contractual and tortious claims, for clients around the world with respect to a wide range of products, including pharmaceuticals, medical devices, cosmetics, electrical and electronic products. Cécile also has experience in advising clients on regulatory, product safety and compliance issues. This work includes coordinating on an international basis large recalls of consumer products on behalf of market-leading international brand names, advising on litigation risks, coordinating advice from local counsel in multiple jurisdictions, and managing authority notifications across Europe and worldwide.

Cécile plays an active role in developing a "Global Issues Initiative" which Hogan Lovells and the Product Liability Advisory Council (PLAC) in the US are working on together. This includes running a series of webinars on a range of global product liability and safety issues. Cécile is also a member of IPLR's International Co-ordination Panel and of IPLR's editorial team.

See page 26 for Cécile's article "Part 36 offers: genuine attempt to settle or disguised request for total capitulation?"



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Charles-Henri is a Senior Associate in the Litigation practice of Hogan Lovells' Paris office and is a member of the firm's international life sciences team. Over the past six years, Charles-Henri has worked extensively with French and international pharmaceutical companies, biotech companies and medical devices manufacturers in commercial litigation, product liability and group actions. He notably represents companies in mass litigation cases involving thousands of plaintiffs and has specific experience in complex product liability matters, particularly multi-jurisdiction bodily injury cases and the cross-border coordination these cases require. Charles-Henri works on a daily basis with colleagues within the firm; he was seconded to our London Litigation practice in 2013.

As a graduate from Sciences Po Paris and HEC Paris business school, Charles-Henri understands the business objectives of our clients in this complex regulatory environment. Charles-Henri is a member of the young lawyers committee of the association of defence counsel DRI International. He regularly publishes articles regarding both legal and procedural developments such as, in this edition, the introduction of class actions mechanisms in France.

See page 5 for Charles-Henri's article "Class actions in health-related matters: they're here – for better or for worse"

In this issue...

1 Overview

FEATURE

2 EU product safety reporting in focus: notifications via RAPEX still on the rise

Dr Sebastian Polly and Leopold Borst (Munich), Anthea Davies and Ellie Pszonka (London) report on the ongoing rise of reports of product safety risks via RAPEX. With regulators placing increasing emphasis on the enforcement of product safety laws, it's a trend that's likely to continue. Companies need to be diligent to ensure their products are safe and compliant, and that they stay ahead of regulatory changes.

EUROPE – FRANCE

5 Class actions in health-related matters: they're here – for better or for worse

Health-related class action procedures have just been introduced in France. Charles-Henri Caron and Bérengère Moin (Paris) report on this new procedural mechanism and highlight its potential weaknesses.

10 Hepatitis B vaccination litigation: proof of causation and defect examined by the Court of Justice of the European Union

In France, Cécile Derycke and Isabelle Chivoret (Paris) report on a recent decision of the French Supreme Court, where a request for a preliminary ruling was submitted to the Court of Justice of the European Union (CJEU). The case concerned proof of defect and causation under the Product Liability Directive.

EUROPE – GERMANY

14 New data watchdog on the way for Germany: consumer associations to bring representative actions

The draft bill on the right of consumer associations to bring representative actions in the interests of protecting consumer data will soon enter into force. Since it was first introduced in February 2015, a number of amendments have been made to this important new legislation. Matthias Schweiger and Vera Wichers (Munich) summarise these changes and explain their impact.

EUROPE – NETHERLANDS

16 Causality in the spotlight: can a drug cause a gambling addiction?

A recent case in the Dutch Court of Appeal examined the concepts of "general causality" and "specific causality", neither of which are common terms in Dutch case law. Karen Jelsma and Noor Hogerzeil (Amsterdam) sum up the facts and discuss the key points considered by the Court in its judgment.

EUROPE – SPAIN

19 A new standard of care in product liability cases? Spanish Supreme Court decision could be a game-changer

In a recent case involving exposure to asbestos, the Supreme Court introduced new criteria that could transform the standard of care applied in product liability cases. As Carolina Revenga and Gloria Torres (Madrid) point out, the standard of care seems to have been raised. It may no longer be enough to show that one has acted diligently. "Extreme diligence" may be needed to avoid liability.

EUROPE – UK

21 Lord Justice Jackson proposals: fixed costs to be extended to higher value civil claims?

Jackson LJ's proposal for a fixed cost framework for claims up to £250,000 could be implemented this year. As Matthew Felwick (London) points out, this would bring England and Wales in line with other jurisdictions and could, if considered a success, be extended to larger, more complex claims in the future.

24 Update: access to Medical Treatments (Innovation) Act 2015-2016

Significant changes were made to the Access to Medical Treatments (Innovation) bill as the controversial first draft made its way through Parliament. Matthew Felwick (London) summarises the recent developments to the legislation which recently made it onto the statute books.

26 Part 36 offers: genuine attempt to settle or disguised request for total capitulation?

Cécile Burgess and Danielle Secher (London) discuss a recent High Court judgment examining "Part 36 offers". Under the English Civil Procedure Rules, these are designed to encourage settlements, and put offerees at risk of extra cost penalties if they fail to accept. The case looked at what's needed to make a Part 36 offer valid and effective, and when such an offer will be viewed as a genuine attempt to settle.

29 UK's consumer product recall system: review finally released

The long-awaited review of the UK's consumer product recall system has recently been released. Chaired by Lynn Faulds Wood, it makes a number of recommendations for improving enforcement and implementation of the regulatory regime in this area. Anthea Davies (London) sums up these recommendations – and the government's responses to them.

NORTH AMERICA – US

31 Amendments to chemical regulation: increased federal oversight likely

Proposed amendments to the Toxic Substances Control Act 1976 will increase the Environmental Protection Agency's ability to investigate and regulate the manufacture and use of chemicals in the US. While regulation of chemicals was previously a focus for state and local agencies, this signals a shift towards increased federal oversight. Phoebe Wilkinson, Samuel Zimmerman, and Alan Mendelsohn (New York) summarise the amendments and assess the implications for US chemical regulation.

Overview

As this publication moves into its seventeenth year of publication, our focus turns to some of the controversial product liability questions facing the European judiciary. These issues are fast becoming the common subject matter of our most senior courts in Europe.

In the Netherlands, the Dutch Court of Appeal has been grappling with the question of liability for gambling addiction alleged to have been caused by use of a drug (page 16). This case highlights the challenges faced by a court when trying to assess the questions of product defect and causation when dealing with a complex pharmaceutical product.

The question of causation in the context of pharmaceutical-related product liability cases has in fact, now been referred to the Court of Justice of the European Union, the highest court in Europe, in a case involving an alleged link between a vaccine and certain diseases (page 10). In this hugely significant case, the European Court has been asked to determine to what extent a court needs to take into account the state of scientific evidence when considering questions of causation. Whilst the outcome from this case is pending, the result will likely have a serious impact not only on companies within the life sciences industry, but for manufacturers across many sectors.

In Spain, the Supreme Court has rendered a decision on asbestos liability, seemingly extending traditional principles to introduce a need, in some circumstances, for a company to take “extreme diligence” to avoid harm (page 19). Again, a case that risks affecting product manufacturers well beyond the context in which the case itself arose.

In France, we see the introduction of class action procedures for “health-related claims” (page 5). An important development that affects liability risks for manufacturers of products such as pharmaceuticals, medical devices and, interestingly, cosmetic products, France has long been considered a leader in Europe in the field of innovative procedural mechanisms for the commencement of grouped claims before the courts. This latest development, if successful, may spread over time across Europe.

Our Feature article in this issue of *International Product Liability Review* is an overview on the trends in the reporting of dangerous consumer products via the European Commission's RAPEX regime (page 2).

The findings are interesting, showing that the high level of reporting over the past years is continuing. Whilst the growth pattern now appears to have abated, the number of products reported into the system remains high, and a number of national member state authorities are emerging as particularly active in this area. A finding that is consistent with the Hogan Lovells team's own experience in working with clients dealing with regulatory challenges raised by authorities in Europe.



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