

# International Product Liability Review

---

Issue 61

## Contents

---

|   |    |                    |    |
|---|----|--------------------|----|
| Overview  | 1  | Europe – Poland    | 18 |
| Feature – Product liability law in Mexico: still under construction | 2  | Europe – UK        | 21 |
|   |    | North America – US | 22 |
| Europe – EU   | 6  | International      | 27 |
| Europe – France   | 8  |                    |    |
| Europe – Italy  | 14 |                    |    |
| Europe – Netherlands  | 16 |                    |    |

DECEMBER

2015

## About our Product Litigation, Compliance and Mass Torts Practice

Hogan Lovells has the leading international product liability practice covering all aspects of product liability, compliance and mass torts. We have experience of acting for clients around the world in respect of a wide range of products 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, compliance and mass torts practice, please visit our website at [www.hoganlovells.com](http://www.hoganlovells.com) or contact the Product Liability Group Leader, Rod Freeman, at [rod.freeman@hoganlovells.com](mailto: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 liability and product safety 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:

Rod Freeman  
[rod.freeman@hoganlovells.com](mailto:rod.freeman@hoganlovells.com)

Valerie Kenyon  
[valerie.kenyon@hoganlovells.com](mailto:valerie.kenyon@hoganlovells.com)

Cécile Burgess  
[cecile.burgess@hoganlovells.com](mailto:cecile.burgess@hoganlovells.com)

Anthea Davies  
[anthea.davies@hoganlovells.com](mailto:anthea.davies@hoganlovells.com)

Caroline Hibberd  
[caroline.hibberd@hoganlovells.com](mailto:caroline.hibberd@hoganlovells.com)

With thanks to Samantha Tharle

This issue of *International Product Liability Review* is produced with the support of our International Co-ordination Panel:

Jacopo Bartolomeo (Milan)  
[jacopo.bartolomeo@hoganlovells.com](mailto:jacopo.bartolomeo@hoganlovells.com)

Pauline Faron (Paris)  
[pauline.faron@hoganlovells.com](mailto:pauline.faron@hoganlovells.com)

Valerie Kenyon (London)  
[valerie.kenyon@hoganlovells.com](mailto:valerie.kenyon@hoganlovells.com)

Colleen McKnight (Baltimore)  
[colleen.mcknight@hoganlovells.com](mailto:colleen.mcknight@hoganlovells.com)

Laura-Jean Van De Ven (Amsterdam)  
[laura-jean.vandeven@hoganlovells.com](mailto:laura-jean.vandeven@hoganlovells.com)

Eugenio Vázquez (Madrid)  
[eugenio.vazquez@hoganlovells.com](mailto:eugenio.vazquez@hoganlovells.com)

Vera Wichers (Munich)  
[vera.wichers@hoganlovells.com](mailto:vera.wichers@hoganlovells.com)

Phoebe Yan (Shanghai)  
[phoebe.yan@hoganlovells.com](mailto:phoebe.yan@hoganlovells.com)

## Meet the team

We are pleased to introduce two of the authors who have contributed to this edition of *International Product Liability Review*: Luis Omar Guerrero Rodríguez (Mexico City) and Laura-Jean van de Ven (Amsterdam).



**LUIS OMAR GUERRERO RODRÍGUEZ**

**Partner – Mexico City**

omar.guerrero@hoganlovells.com



Luis Omar Guerrero Rodríguez is a partner in the Mexican office. Based in Mexico City, Omar is the co-head of the arbitration and litigation practice and also co-heads the antitrust practice of our Mexican office. In the book *Outliers*, author Malcolm Gladwell says that the key to achieving world class expertise in any skill, is, to a large extent, a matter of practicing for roughly 10,000 hours. Omar has embraced this famous "10,000-Hour Rule"! He has been recognised by Chambers & Partners, Who's Who and Legal 500 as a leader in his practice.

Omar is convinced of the importance of being a team-player, providing bold solutions for clients and the merits of being a fierce competitor. Omar is the author of various publications and handles complex litigation matters involving torts, breach of contracts, moral damages, product safety and product liability.

*See page 2 for Omar's article "Product liability law in Mexico: still under construction"*



**LAURA-JEAN VAN DE VEN**

**Associate – Amsterdam**

laura-jean.vandeven@hoganlovells.com



Laura-Jean van de Ven is an Associate in the Hogan Lovells Amsterdam litigation practice. Laura-Jean specialises in commercial litigation and product liability (including class action litigation). Her litigation practice focuses on medical devices, pharmaceuticals, consumer goods, and hazardous substances. Laura-Jean is an advisor to Dutch and international clients on European and international product liability, product safety issues and product recalls. She also regularly appears before Dutch civil courts in the context of commercial disputes (enforcement and termination of contracts, etc.).

As a member of the Amsterdam product liability team, Laura-Jean has represented several medical device manufacturers in claims alleging damages from defective medical devices. The Product Liability Litigation practice of the Amsterdam office is involved in various complex and cross-border product liability cases in which the department also cooperates closely with colleagues from the other Hogan Lovells offices.

*See page 16 for Laura-Jean's article "Product owners: Beware! You could be liable for a product defect"*

## In this issue...

### 1 Overview

#### FEATURE

### 2 Product liability law in Mexico: still under construction

Luis Omar Guerrero Rodríguez and Luis Enrique Graham Tapia (Mexico City) report on developments in the area of product law in Mexico where recent case law and amendments to federal statutes are ushering in an era of enhanced protection for consumers.

#### EUROPE – EU

### 6 Safe Harbor's invalidated: what next?

Following Safe Harbor's invalidation by the Court of Justice of the European Union, organisations that previously relied upon this framework to validate transfers of data from the EU to the US could be exposed to claims that these transfers were unlawful. Winston Maxwell (Paris), Dr Stefan Schuppert (Munich), Harriet Pearson and Bret Cohen (Washington DC), and Eduardo Ustaran (London) recommend practical steps for companies in a post Safer Harbor world.

#### EUROPE – FRANCE

### 8 Still no need for claimants to mitigate damages in personal injury cases

In France, there's no obligation for personal injury claimants to mitigate the loss they suffer. A recent case in the Supreme Court reinforces this principle. Charles-Henri Caron and Paul Boutron (Paris) report.

### 11 Greater clarity on which statute of limitation applies in French product liability claims

A recent decision by the French Supreme Court examined the question of which statute of limitation applies in product liability claims for products marketed before the implementation of the PL Directive in France in 1998. Christophe Garin and Isabelle Chivoret (Paris) report on a case which involved an allegedly defective hepatitis B vaccine.

#### EUROPE – ITALY

### 14 The trivalent vaccine does not cause autism: key decision by the Bologna Court of Appeals overturns earlier Italian case law

A key decision could herald a significant change of direction in the case law surrounding a possible causal link between certain types of vaccination and autism in children. Christian Di Mauro and Jacopo Bartolomeo (Milan) review the judgment by the Bologna Court of Appeals and assess its potential impact on future case law in this area.

#### EUROPE – NETHERLANDS

### 16 Product owners: Beware! You could be liable for a product defect

Karen Jelsma and Laura-Jean van de Ven (Amsterdam) report on an interim judgment of the District Court of Oost-Brabant which has potentially far-reaching consequences for product owners. The Court's decision (involving an exclusive right of use for a product) states that even if an owner doesn't know about a defect in a product, they can still be liable for any damages arising from that defect.

#### EUROPE – POLAND

### 18 New powers for Poland's Office of Competition and Consumer Protection

Robert Gago, Beata Balas-Noszczyk and Anna Tarasiuk (Warsaw) report on imminent changes to the consumer protection regime, which are likely to have a significant impact on traders in Poland. Amongst other developments, so-called abusive clauses will be more clearly defined and the Office of Competition and Consumer Protection (OCCP) will have far wider powers.

## In this issue...

### EUROPE – UK

#### 21 Crackdown on claims culture?

In a drive to bring down the cost of motor insurance, the government recently revealed plans to limit the sums that can be claimed for minor road accidents. As Matthew Felwick and Aine McEleney (London) report, the current proposals raise a number of questions. These include whether or not the proposed increase in value of personal injury claims that can be allocated to the small claims track will be limited to motor injury claims.

### NORTH AMERICA – US

#### 22 Bring your own smartphone: using digital technologies in clinical trials

Yarmela Pavlovic (San Francisco), Robert Church (Los Angeles), Heidi Gertner, Philip Katz, Komal Karnik and Katelyn Ruiz (Washington) report on a recent FDA request for comments on the use of digital technologies in clinical trial research. It's a development that highlights the growing need for pharmaceutical, biotech and medical device companies to integrate smartphones, tablets, and wearables into their operations.

#### 24 "The Yates Memo": DOJ puts individuals in the spotlight in corporate misconduct cases

Guidelines recently issued by the US Department of Justice on individual accountability for corporate wrongdoing (the "Yates Memo") include a rigorous focus on the prosecution of individuals in cases of corporate misconduct. Robert Toll (New York) and Caroline Hibberd (London) review the guidelines and assess their impact for companies involved in product safety cases.

### INTERNATIONAL

#### 27 Hot topics in product safety from the 2015 ICPHSO International Symposium

Hogan Lovells lawyers report from the International Consumer Product Health and Safety Organisation ("ICPHSO") 2015 International Symposium. Recurrent themes at the event included the product safety challenges created by emerging technologies and what regulators need to do to respond.

## Overview

The Hogan Lovells international products practice continues to expand around the world, and this issue features a report from our team on the status of product liability and product safety regulation in Mexico (page 2). It's a legal regime that is very much "still under construction", but as is characteristic of the jurisdictions in that region, risks and challenges for international product manufacturers are increasing. It is particularly interesting to see that concepts based on the protection of human rights are being relied upon by the courts to change the law on liability for injuries in favour of consumers.

In Europe, the dramatic decision of the Court of Justice of the European Union to declare as invalid the EU-US Safe Harbor framework for data protection created shockwaves for businesses around the world (page 6). Data protection and cyber-security are increasingly relevant to product manufacturers as their use of technology and their interaction with markets evolve. This decision affects virtually all companies involved in the supply of products internationally, and responses are needed, as explained in this issue.

In a decision that will surprise many around the world, the French Supreme court has issued a ruling in a personal injury case confirming the position under French law that the plaintiff does not have an obligation to mitigate their damages, and that the defendant will be responsible for all of the damages suffered despite any failure by the plaintiff to mitigate loss (page 8). This position remains controversial amongst legal scholars in France, but the legal position appears to be reasonably well settled, at least for the present time.

It is very much a "sign of the times" that the United States Department of Justice issued the "Yates Memo", setting out new guidelines for the investigation and prosecution of incidents of corporate misconduct, including guidelines on the pursuit of actions against individuals involved in such misconduct (page 24). This has obvious implications for product manufacturers who may have the misfortune of finding themselves in the frame for a regulatory investigation following a product safety crisis or event.

Finally, this issue of *International Product Liability Review* includes a report on the interesting discussions that took place at the 2015 International Symposium of the International Consumer Product Health and Safety Organization (ICPHSO), which was held at the headquarters of Lego in Billund, Denmark (page 27). This event, which featured high level involvement from the European Commission, the US CPSC, and other international regulatory agencies, highlighted the increasing internationalisation of product safety regulation, as well as the strong benefits of active and constructive dialogue between stakeholders as international policies are being discussed and developed. ICPHSO's Annual Meeting is taking place in Washington DC during the week of 29 February 2016, and is a must-attend event for consumer product manufacturers. Hogan Lovells will be there to help lead some of the discussions on international issues for product manufacturers. Hope to see you there! Further information can be found at [www.icphso.org](http://www.icphso.org).



**Rod Freeman**  
London  
[rod.freeman@hoganlovells.com](mailto:rod.freeman@hoganlovells.com)