

# PHARMACEUTICALS AND HEALTHCARE REGULATORY

HARNESSING REGULATORY STRATEGY TO DELIVER INNOVATION

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The sector specialists across our network help some of the world's foremost pharmaceuticals and healthcare companies achieve their strategic goals at critical points in the life-cycle of their most important products, and in their transactions and disputes.

The sector specialists across our network help clients achieve their strategic goals and manage risk in their transactions and disputes, and at critical points in the life-cycle of their most important products.

Our cross-border team also handles major product recall and crisis management, and follow on disputes and investigations, regulatory challenges, procurement disputes, class actions and insurance coverage.

## RELATED CONTENT

[INTELLECTUAL PROPERTY NOTES](#)

[COMPETITION NOTES](#)

[PUBLIC LAW NOTES](#)

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## ACCOLADES

**'The team is highly recommended for their IP and regulatory skills, combining advice and litigation capabilities.'**

***Life Sciences & Healthcare, Legal 500 Italy***

**'A top-tier team, very impressive.'**

***Pharmaceuticals & Biotechnology, Legal 500 UK***

**'The lawyers combine the high quality and sophisticated knowledge of a boutique law firm with the approach, mind-set and language skills of an international firm. So what we get is a combination of high-quality legal advice given to us in a very concise, practical and helpful way'**

***Legal 500, Life Sciences & Healthcare, Italy***

**'Tier 1, Pharmaceuticals & Biotechnology'**

***Legal 500 UK***

**'Band 1, Life Sciences'**

***Chambers Australia***

**'Tier 3, Life Sciences & Healthcare'**

***Legal 500 Italy***

**'Firm of the Year: Patent Strategy & Management'**

***LMG European Life Sciences Awards 2020***

**'Firm to Watch: Litigation & Enforcement'**

***LMG European Life Sciences Awards 2020***

**'Life Sciences Firm of the Year - Italy'**

***LMG European Life Sciences Awards 2020***

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## **RECENT EXPERIENCE**

### **ARIOSIA DIAGNOSTICS**

on the impact of regulatory issues (including CE-marking) on patent litigation concerning their Harmony® non-invasive prenatal diagnostic test

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## **ROCHE AND ABBVIE**

on the European biosimilar regulatory frame work

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## **ROCHE, TAKEDA, ABBVIE, GILEAD AND OTHERS**

on European market access issues, including pricing and reimbursement

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## **GILEAD SCIENCES**

on the Europe-wide dispute concerning the SPC for the HIV drug Truvada, including the implementation of the CJEU decision on combination SPCs

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## **ACHILLES VACCINES**

a leading Italian vaccine-developer on various projects, including the creation of a platform for streamlining the research and development of new vaccines (including against COVID-19) and the start of a collaboration with vAMRes Lab at Toscana Life Sciences (TLS) Foundation (based in Siena, Italy) on a research project for the development of human monoclonal antibodies against COVID-19, with the aim of using them for prophylactic/therapeutic purposes and as molecular baits for the discovery of vaccine antigens

## A GLOBAL PHARMACEUTICALS COMPANY

in relation to the termination of a licence agreement. In particular, on technical and regulatory issues including the impact of data and marketing exclusivity on the interpretation of the agreement

## OUR PEOPLE



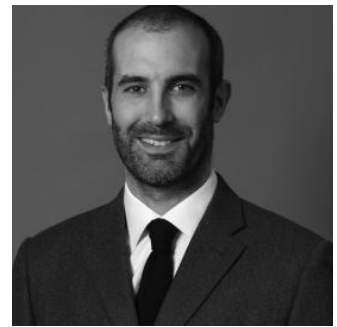
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