

## Hélène Boland

Associate

Brussels

### Biography

Hélène Boland advises clients on European Union and national regulation of medical devices and pharmaceutical products. She assists clients in the different phases of the application process for marketing authorisation of medicinal products and related post-marketing activities and the conformity assessment process for medical devices. She also assists clients in understanding the requirements that will be introduced by the forthcoming entry into application of the new EU medical device regulations and in various aspects of digital health technologies.

As a Belgian qualified lawyer, Hélène regularly advises international companies with complex queries in relation to Belgian or EU law.

Prior to joining Hogan Lovells, Hélène worked as a trainee at the Food Task Force of the European Commission's Directorate General for Competition.

### Latest thinking and events

- News
  - Regulation of COVID-19 Tests in the EU: when do you need to involve a Notified Body?
- News
  - FDA finalizes policy on multi-function medical devices' premarket submissions



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### Languages

Dutch  
English  
French

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### Practices

Medical Device and Technology  
Regulatory

Pharmaceuticals and Biotechnology  
Regulatory

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### Industries

Life Sciences and Health Care

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### Education and

- News
  - COVID-19- AFMPS reviews its export ban on certain medicinal products outside the EEA
- News
  - Belgium follows the FDA's approach on the reprocessing of surgical masks and FFP2/FFP3 facemasks
- News
  - New European Commission's guidance document on medical devices and IVDs in the COVID-19 context
- News
  - EU suspends tariffs on medical equipment

## admissions

### Education

Master of Law, Université Libre de Bruxelles, 2017

LL.M in International Investment and Trade Law, University of Maastricht, 2015

Bachelor of Laws, University of Maastricht, 2014

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### Bar admissions and qualifications

Brussels

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