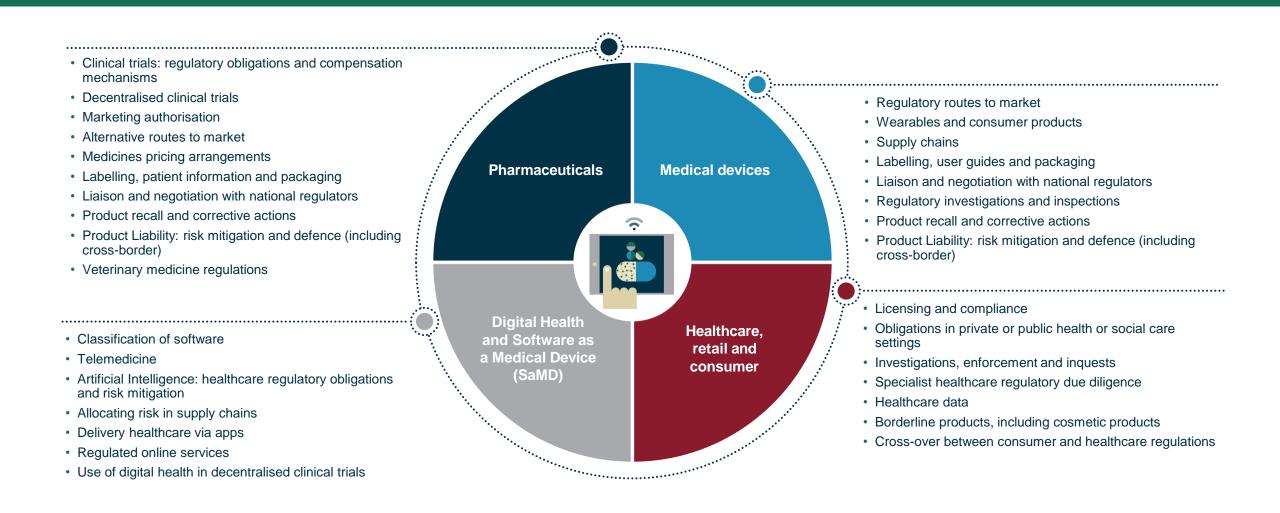
# Life Sciences and Healthcare Regulatory and Compliance





# **Examples of our work**

#### Pharmaceuticals

- Advising a manufacturer on the regulatory regime concerning orphan drugs and alternative routes to market
- Providing advice to companies in relation to the production, manufacture and distribution of cannabidiol (CBD)
- Assisting a pharmaceutical company on its options regarding classification of medicines and obligations under UK pricing rules, including the voluntary scheme for branded medicines pricing and access (VPAS)

## **Medical Devices**

- Advising a multi-national on the regulatory regime affecting its device and negotiations with the UK Medicines & Healthcare products Regulatory Agency (MHRA) on product classification
- Providing medical regulatory advice to a PE house on investment into a company producing a novel medical device
- Advising a digital technology company on whether an algorithm in an app constituted a medical device

#### **Digital Health and Software**

- Advising a digital primary care provider on EU and UK health and data regulations, preparing global contracting documentation and advice on insurance
- Providing advice to investors in a medical device company focussed on products incorporating software into medical devices
- Supporting a company with its contractual negotiations to allocate regulatory risk and liability within its supply chain

## Healthcare, retail and consumer

- Advising a leading provider on regulatory issues relating to mobile research and decentralised clinical trials
- Providing regulatory advice to a company leasing equipment to NHS hospitals
- Assisting a newly founded company providing care home facilities on its regulatory obligations, including under the Care Quality Commission (CQC)





Vladimir Murovec

Counsel, Belgium T +32472607628 Vladimir.murovec@osborneclarke.com



Thomas Devred Partner, France T +33 1 84 8 24106 thomas.devred@osborneclarke.com



**Tim Reinhard** Partner, Germany T +49 89 5434 8024 tim.reinhard@osborneclarke.com



Maria Grazia Medici

Partner, Italy T +39 06 3269 5015 mariagrazia.medici@osborneclarke.com



Agnieszka Sztoldman

Counsel, Poland T +48 22 152 42 43 agnieszka.sztoldman@osborneclarke.com



Silvia Steiner Socio/Partner, Spain T +34 93 419 18 18;ext=250 silvia.steiner@osborneclarke.com



Will James Partner, UK T +44 207 105 7774 will.james@osborneclarke.com

