EU Pharmaceutical Law Forum

EU PHARMACEUTICAL LAW: INDUSTRY REPORT 2019

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INTRODUCTION

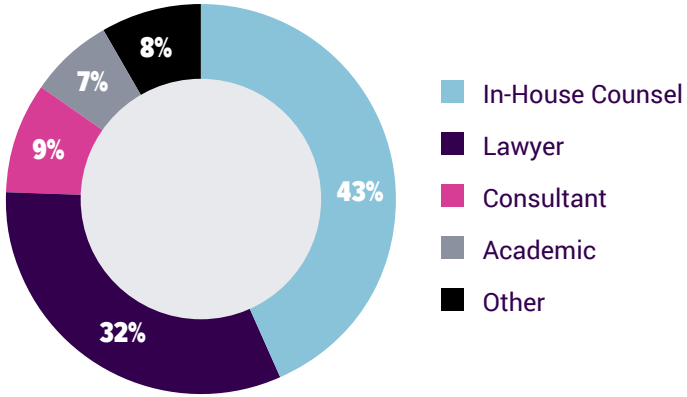
The pharmaceutical industry is facing an unprecedented level of disruption and the role of legal professionals in the industry is rapidly evolving to keep pace with the changing needs of the businesses they support. Rapidly advancing science is being counterbalanced with stricter regulations and challenges to the very core of how innovation is incentivised and funded. Legal professionals sit at the axis of these changes, increasingly tasked with being strategic partners and business enablers in the face of change.

In March 2019, the EU Pharmaceutical Law Forum conducted a survey of legal professionals across Europe. Based on their responses, this report reveals unique insights into the state of the industry in 2019; the hottest potential opportunities, the biggest challenges and how industry insiders are tackling them.

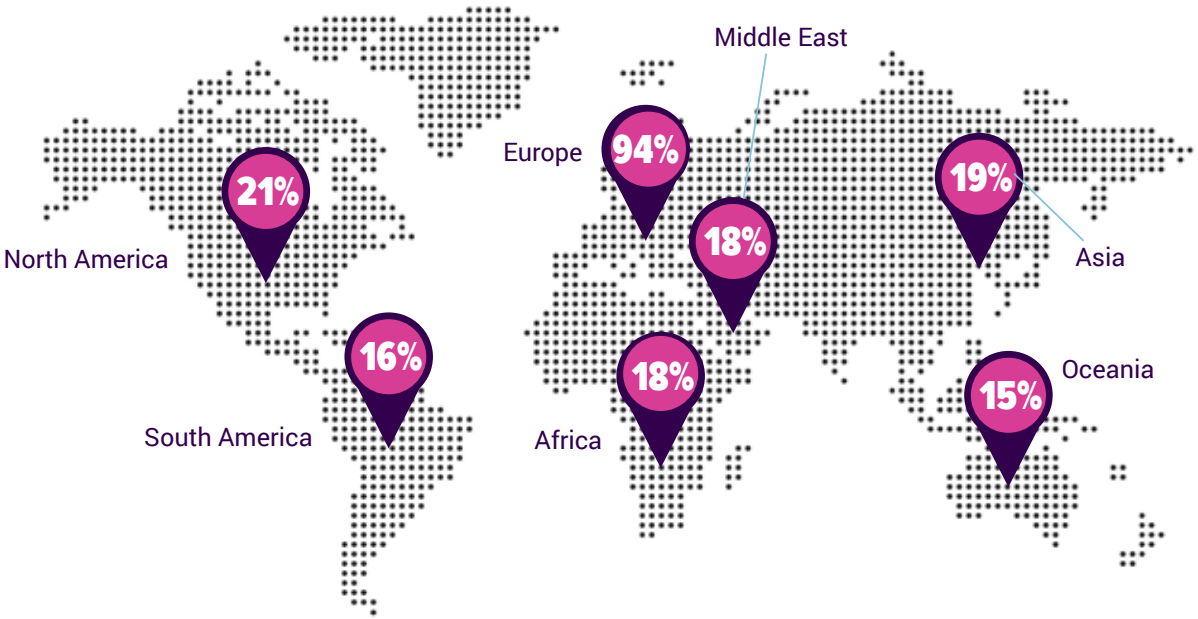
Jerry Temko, Head of Legal, Global Manufacturing for Ferring Pharmaceuticals, consulted on this report. He previously served as Senior Vice President & General Counsel for Astellas Pharma Europe Ltd. and was responsible for setting strategy and advising senior management on all EMEA legal and compliance matters. He holds M.A. and LL.M. degrees in Law from the University of Cambridge, and is a graduate of the University of Pennsylvania where he received B.A. and M.A. degrees in International Relations. Jerry is a member of the New York Bar and is Executive Director & Founder of the EU Chapter of PILLS, an in-house pharmaceutical industry lawyers association.

RESPONDENT DEMOGRAPHICS

Job function

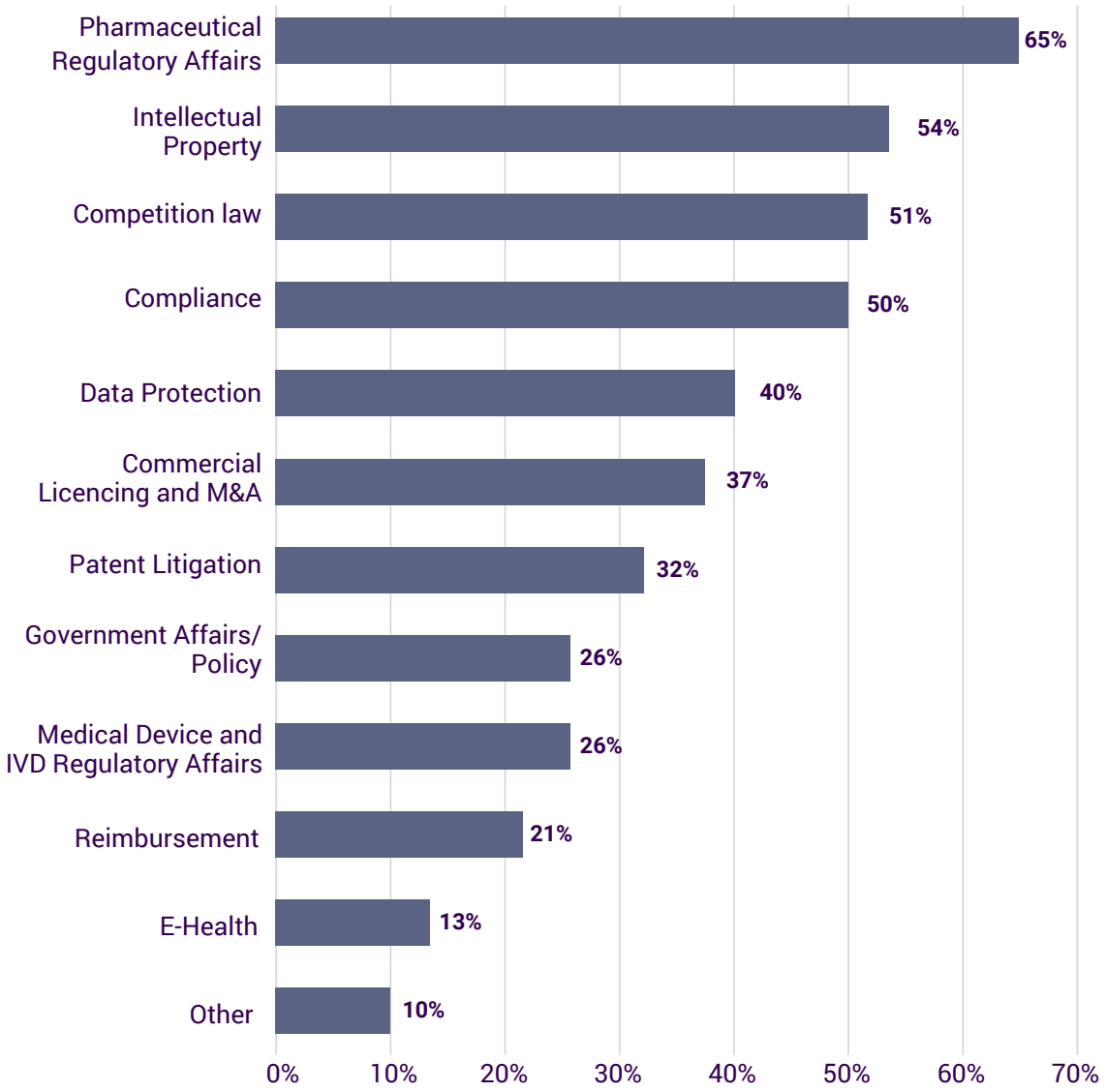


Regions covered in your role

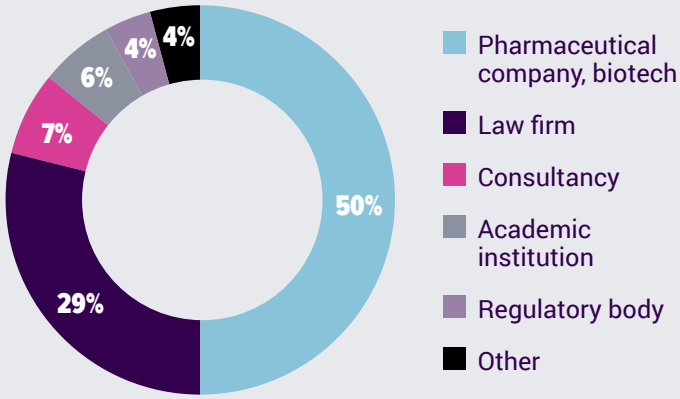


RESPONDENT DEMOGRAPHICS

Which areas of pharmaceutical law do you focus on?



Organization Type



Company size (no. of employees)

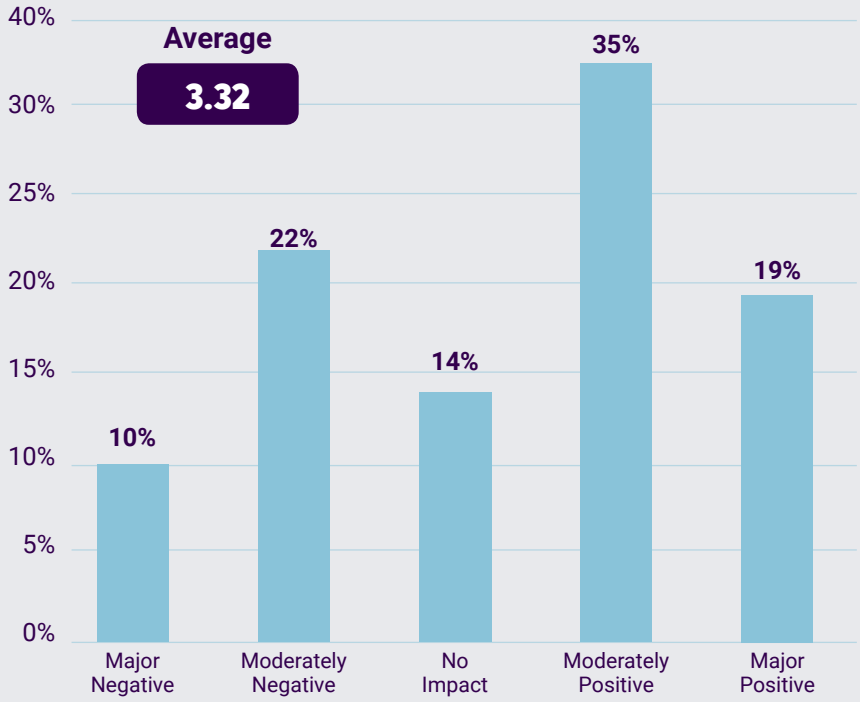
TOP 10: What do you think is the biggest challenge facing legal professionals in the industry?

1. Changes in the regulatory environment
2. New technologies such as AI
3. Pricing
4. Compliance
5. Digitalisation
6. Cost
7. Brexit
8. Covering different regions
9. Data protection
10. Automation

TOP 5: Which European regulations do you think are impacting your business the most?

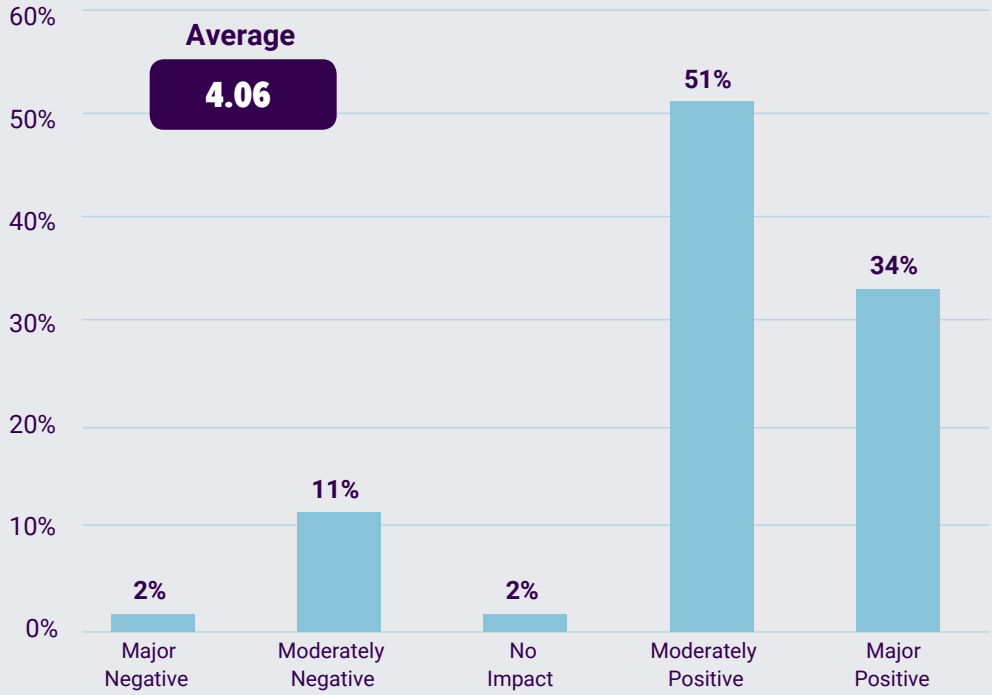
1. GDPR
2. Medical device regulations
3. Competition law regulations
4. Directive 2001/83
5. Unitary Patent System

What impact do you think the manufacturers export waiver for supplementary protection certificates (SPCs) will have on the European IP framework?



*Excluding Not Applicable (5)

What impact do you think greater Health Technology Assessment harmonisation across Europe will have on market access and reimbursement?



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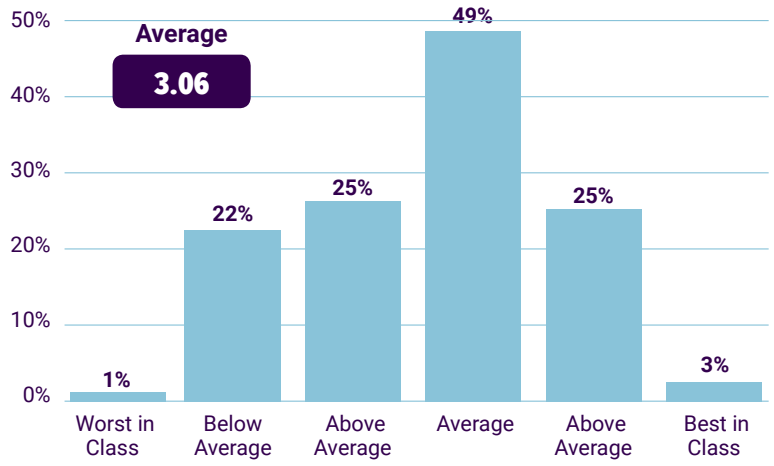
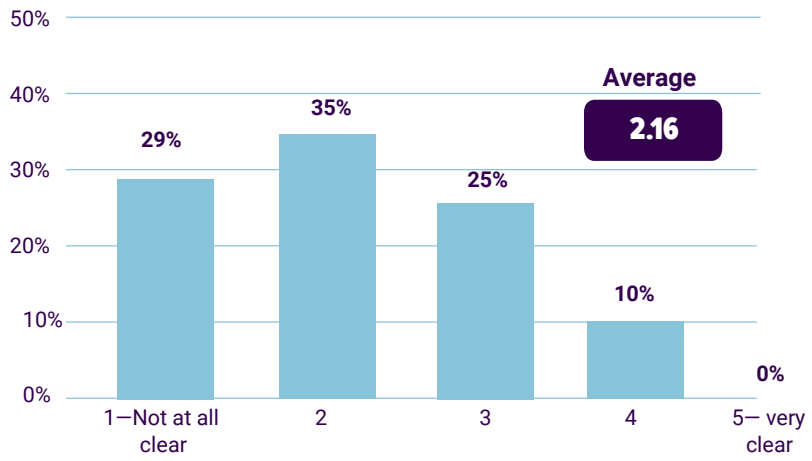
TECHNOLOGY

How well do you think your organisation is embracing digital innovation, AI and e-health compared to others?



How clear are you about regulators' expectations and requirements for e-health and digital innovation in the pharmaceutical industry?



What are the key trends in commercial collaboration and partnering? (Selected responses)

- BIG DATA
- CO-LICENSING
- RISK SHARING AGREEMENTS
- COLLABORATIONS BETWEEN TECH AND PHARMA COMPANIES
- OPEN INNOVATION
- PRICE MODELS
- COMPLEX COLLABORATION BETWEEN DIFFERENT STAKEHOLDER GROUPS AND INTERESTS

What legal / regulatory barriers exist for the adoption of RWE in Europe? (Selected responses)

"Access and physical collection of large amounts of data, processing of personal data and unreliability of the sources."

"Clinical study design - many stakeholders still want to see results from randomized controlled trials."

"Different pricing and reimbursement policies and rules across the European Union."

"Lack of relevant regulations."

60%

think the use of RWE in the EU regulatory process will speed up the drug approval process

"The challenge will be convincing a regulator RWE is of sufficient weight and robustness to reduce clinical data burdens."

"RWE is not as described by regulatory requirements."

"Unharmonized local health systems."

"Consensus that randomized controlled trials remain the gold standard for demonstrating the efficacy and safety of medical products and treatments."

"Validation of the data. In QA validation of data and its input is key so for RWE is this possible?"

REGULATORY AUTHORITIES

If you could ask the European Commission one question anonymously, what would it be? (Selected responses)

- Can you find a way where UK science can still be practically involved as it was before Brexit?
- Do you appreciate the value of innovative medicines?
- Does the EC see the need for adopting IP law in respect to new technologies (eg. combining patent law with copyright for computer programs)?
- What are the future plans for greater regulatory harmonisation?
- How do you intend to deal with excessive pricing cases?
- Is it possible to achieve a reimbursement system in the EU for rare disease?
- What do they really think about RWE?

If you could ask the EMA one question anonymously, what would it be? (Selected responses)

- Are there already specific plans for the EU HTA process and how will it look?
- Can you find a way in which UK can still have access to the databases?
- Can you provide insight into Pharma 2025 or Pharma 2030?
- What's the policy focus for 2019?
- Do you see the need for new regulations in respect of biosimilars, which in my opinion are not the same as generics?
- Does the EMA interact with the Commission in the investigation on antitrust cases in the pharmaceutical sector?
- What do they really think about patent evergreening?
- When can we expect more guidance on how to overcame the similarity concept between two orphan drugs?

BREXIT

What impact do you think Brexit will have on your business?

Why do you think Brexit will have a negative impact on your business? (Selected responses)

"The UK has always been a hub for legal services market and Brexit may change the landscape."

"Disruption to normal business practices, legal uncertainty and the evisceration of many years of negotiation aimed at greater harmonization."

"The UK is a crucial point for many companies, particularly in med dev. Brexit will affect centralized procedures, taxation, payments and cost of cooperation."

"The UK being outside the robust European framework for medicinal products is a loss for all stakeholders."

"London has been a hub for all legal work emanating from the US and from Europe (in general), this will likely change and work flow will become more fragmented over Europe."

"Increased complexity of the Supply Chain and so increased opportunity for errors."

"Increased workload to comply with affected Brexit changes."

"Massive investments have been made to overcome difficulties which is a waste of time and money."

"Participation of UK based companies in European R&D projects will probably be reduced."

"Splitting of harmonised procedures/common practices and establishing new functions/ways of workings will need additional money for development and registration of Gx products, as well as additional time to put the products on the markets."