

Brexit, IP and the Life Sciences sector

Dr Martin Turner

Policy and Projects Manager, BioIndustry Association

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About the BIA

- **Trade association for bioscience** – over 300 members
 - We develop policy and advocate for our sector
 - We enable partnerships within and beyond our sector
 - We support companies to grow with business solutions
- We cover a wide range of policy areas
 - IP, tax and finance, regulation, access to medicines, animal research, GM etc.



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Characteristics of the Life Sciences Sector



- **Long R&D timelines** – typically greater than 10 years
- **High cost** – approx. £1 billion for a new medicine
- **High failure rate** – 9/10 that enter human trials do not reach market
- **Highly regulated** – national and EU-level
- **Medicine prices negotiated with governments** – varies widely across EU
- **UK is a small drugs market** – 3% of global market (EU = 28%)

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IP issues for the Life Sciences Sector

- IP protection is closely entwined with medicines regulation
- Supplementary Patent Certificates (SPCs) and Paediatric & Orphan designations all provide patent life extensions
- Regulatory data exclusivity
- Parallel trade and Exhaustion of Rights
- The Unitary Patent and Unified Patent Court

What the Life Sciences sector requires

- Preference for a close regulatory alignment with Europe for medicines.
- This means continuing the current IP system
- We need an arrangement that works for patients, the UK and EU regulatory authorities and the manufacturers of medicines.
- Transitional arrangements for the UPC Agreement

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mturner@bioindustry.org