

Regulatory Consequences of Brexit

Peter Feldschreiber

4 New Square

1. Pharmacovigilance

- EMA responsible for good pharmaceutical practice and causation of safety related events across europe
- Evolved infrastructure for rapid evaluation across all member EU and EEA states
- Can act on changes in risk-benefit robustly /timely manner

2. Complex, innovative products

- EMA expertise to issue MA for intractable diseases – e.g. cancer, MS, cystic fibrosis
- Decoupling UK regulatory system – delays and added costs to market in UK – slower access for patients and increased costs to NHS
- UK no longer automatically complies with amendments to Medicines Directive, e.g. Clinical trials and pharmacovigilance

3. Product Liability/Consumer Protection

- Unclear if EU legislation re Product liability and General Product Safety Law remains enshrined in UK law
- Even if existing medicines legislation consolidates into UK law, no longer subject to automatic updates as EU law adapts to changing landscape e.g. Personalised precision medicines, early access development routes etc.

4. Development of Innovative Medicines

- Taxonomy of disease changing – pathologies defined on molecular mechanisms rather than target tissues
- Precise/personalised medicines : target markets shrink
- Public health imperative to accelerate approval
- Innovative licensing schemes – conditional licensing, adaptive trials; need to evaluate benefit risk on basis of smaller clinical data base

5. Risk Benefit

- Smaller clinical data base
- Lower signals of safety related adverse events
- Lower statistical power to evaluate efficacy/effectiveness
- May need composite studies to maximise statistical power to evaluate safety and efficacy earlier in clinical development

6. Brexit effect

- Lose access to infrastructure to monitor safety efficacy post marketing
- Increased risk of new therapies being delayed in accessing UK market
- Delay in identifying and acting on safety signals