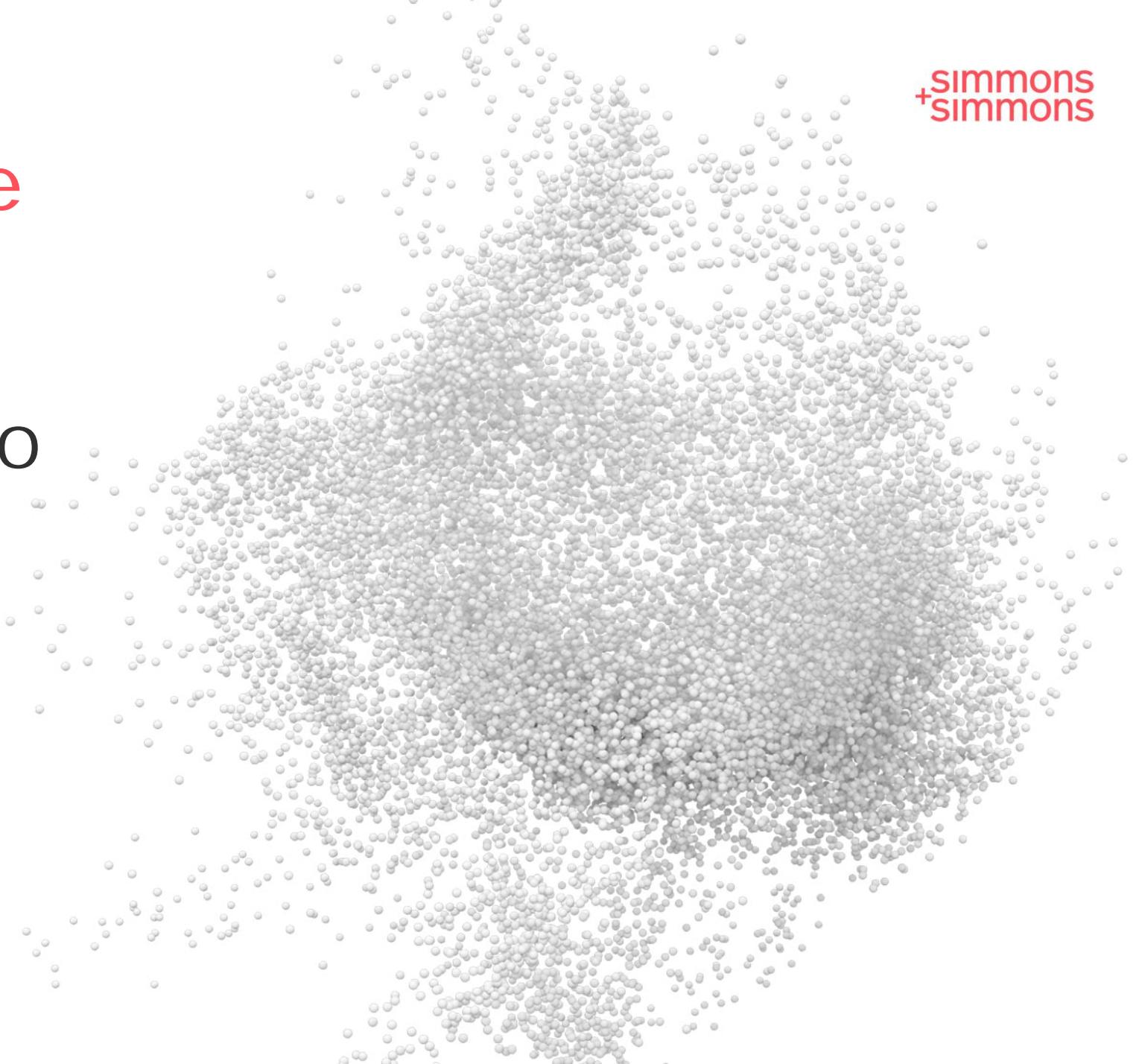


# Healthcare and life sciences: Navigating a hard Brexit scenario

29 October



# Regulatory



1

## General legal considerations

- Withdrawal Agreement, 19 October 2019
- Pending negotiations on future relationship
- In UK: “Retained EU-law”... and potential “rectifying” legislation (Medicines and Medical Devices Bill)
- Specific caution on Northern Ireland
- ... “Any Brexit deal better than no deal” ?

2

## Regulated health products

- Separate regulatory authorities means separate reviews
- **Medicinal products**
  - Marketing authorisations, manufacturing and supply
  - Clinical trials
  - Pharmacovigilance
- **Medical devices**
  - Marketing MDs in EU
  - Marketing MDs in UK



# Regulatory



3

## Healthcare professionals and research programme



- HCPs might have difficulty travelling (+ Covid-19 context): risk for access to healthcare
- Seeking mechanisms to allow UK scientists to support and access EU life sciences programmes, and overcome data transfer issues

4

## Pricing and reference countries



- UK used as reference country for reference pricing in EU
- EU countries used for reference pricing in UK



# Intellectual Property

## How will IP rights will be affected?

### Patents

- No change for granted or pending European patents
- SPC system continues but may diverge - export/stockpiling waiver
- UK withdrawal from UPC - new system in force (without the UK) once Germany ratifies

### Trade marks and designs

- Trade marks and designs most affected
- Existing registered EUTMs and RCDs automatically cloned in UK – but not applications
- EUTMs, RCDs and UCDs continue in EU
- National rights still available

### Copyright and database rights

- Copyright subject of international treaties so Brexit will have little effect
- Continued reciprocal protection for copyright works between the UK and the EU
- Database right – UK companies may no longer hold EU database right (and vice versa)

### Trade secrets

- New Directive implemented in UK in June 2018
- Law unlikely to change in the UK as a result of Brexit

# Intellectual Property

## Additional considerations



### Rights owners take note

- Dual filing for trade marks and designs in EU and UK
- Pending oppositions/cancellation actions at the EUIPO
- Enforcement strategy in EU and UK
- Parallel imports between EU and UK, and customs notices
- Transfer .eu domain names to an EU person
- Review material contracts





# Competition, Antitrust and Trade

## WTO Pharmaceutical Tariff Elimination Agreement

- UK is not yet a signatory but the EU is
- Agreement extends on an MFN basis
- Covers 65% of global pharma trade (2016)
- List of products covered not updated since 2010
- Up to 1,000 finished products and 700 ingredients not currently included
- Zero tariffs ≠ zero checks – delays at border are inevitable

## Merger control

- Active CMA in pharma cases
- Parallel UK and EU merger control regimes with their own jurisdictional thresholds
- Initial similarities likely but divergence inevitable
- CMA intends to exert its presence on a global stage and show it is capable of reaching its decisions on its own analysis that may not align with EC or FTC

## Antitrust

**Parallel trade:** Goods exhausted in UK but not in EEA: level playing field issues in Northern Ireland?

### Distribution rules

- Double vetting at UK and EU levels.
- EU position no longer a safety net?

### Excessive pricing

- Policy tool
- Activist CMA: one of the first points of UK-EU divergence?

# Tax



“Keeping the goods moving” – addressing **indirect tax (VAT, customs)** issues to manage the post-Brexit supply chain



Certain assets and regulated activities/personnel relocating from the UK to an EU jurisdiction – assessing the risk of **exit taxes**



Other changes to operating model and supply chain model to adapt to the post-Brexit environment – analysing the longer-term impact on **transfer pricing**



What hard Brexit could mean for **EU and UK tax policy** initiatives

# Corporate governance



Establishment on  
the continent:  
where to go?



Corporate Governance:  
Rijnland-model vs  
Anglo-Saxon model



Employee  
participation rights

Thank you!

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