ABHI

Association of British HealthTech Industries

Brexit – MedTech Implications

July 2018

Medical Technologies

History and Industry Asks…

HOTEU; April 2017; Summary

ABHI's recommendations represent a clear view for UK MedTech, focused on five themes;

1. Ensuring regulatory stability and leveraging the global reputation of UK regulators
2. Maintaining favourable terms for trading within and outside the EU, along with an integrated domestic policy to support investment, competitiveness and export performance
3. Support for manufacturing, including continuing to address the domestic skills gap and ensuring that the UK can attract the best talent globally
4. Bespoke support for our vibrant SME community
5. Enhanced collaboration with the health and care system.

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History and Industry Asks…

HOTEU; April 2017; Regulatory Recommendations

- Ensuring regulatory stability and leveraging the global reputation of UK
- A pragmatic UK approach to compliance with the current and future European regulation for medical devices
- The UK remaining part of the CE marking regime for MedTech. This requires mutual recognition of the CE-mark between the UK and EU and, where practicable, similar arrangements with other jurisdictions
- UK Notified Bodies (NBs) remain within the existing European network and oversight mechanisms. They should continue to be designated to assess devices for the EU and UK market.
- Authorised Representatives of manufacturers based outside the EU should still be allowed to be domiciled in the UK.
- MHRA retains influence over, and oversight of, the EU regulatory system, through formal engagement with the European Commission's new stakeholder body, the Medical Devices Co-ordination Group (MDCG), and has full access to Eudamed.
- MHRA increases influence over global regulatory harmonisation, through UK membership of the international medical device regulators forum (IMDRF).

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History and Industry Asks…

HOTEU; April 2017; Regulatory Recommendations

- Continued application of International Standards for Quality Management Systems (ISO 13485) and Risk Management (ISO 14971)
- An assessment of the training places available to support MedTech companies and a focus on the training of Regulatory Affairs professionals.

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History and Industry Asks…

HOTEU; April 2017; Trade Recommendations

- Ensure free trade with Europe on the most beneficial terms possible
- Protect other Free Trade Agreement benefits with non-EU countries
- No increased customs duties against imports into the UK
- Ensure UK Customs laws facilitate trade without onerous barriers to duty reliefs or fair customs treatments
- Align regulation to facilitate trade
- Minimise any increased administrative costs and border delays
- Allow transition measures to provide for a reasonable time frame for change implementation without resulting cost increases
- Facilitate less regionalisation/duplication of funding and human resource for exporters
- Increased grant funding for SMEs to support export activity
- Introduce a UK Export Tax Credit Scheme.

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History and Industry Asks…

HOTEU (update); January 2018; Regulatory Recommendations

- The UK remaining part of the CE marking regime for MedTech. This requires mutual recognition of the CE-mark between the UK and EU and, where practicable, similar arrangements with other jurisdictions
- UK Notified Bodies (NBs) remain within the existing European network and oversight mechanisms. They should continue to be designated to assess devices for the EU and UK markets
- Authorised representatives of manufacturers based outside the EU should still be allowed to be domiciled in the UK
- MHRA to remain formally engaged with the European Commission's new stakeholder body, the Medical Devices Co-ordination Group (MDCG), and has full access to the Eudamed database, so retaining insight and influence over the EU regulatory system.

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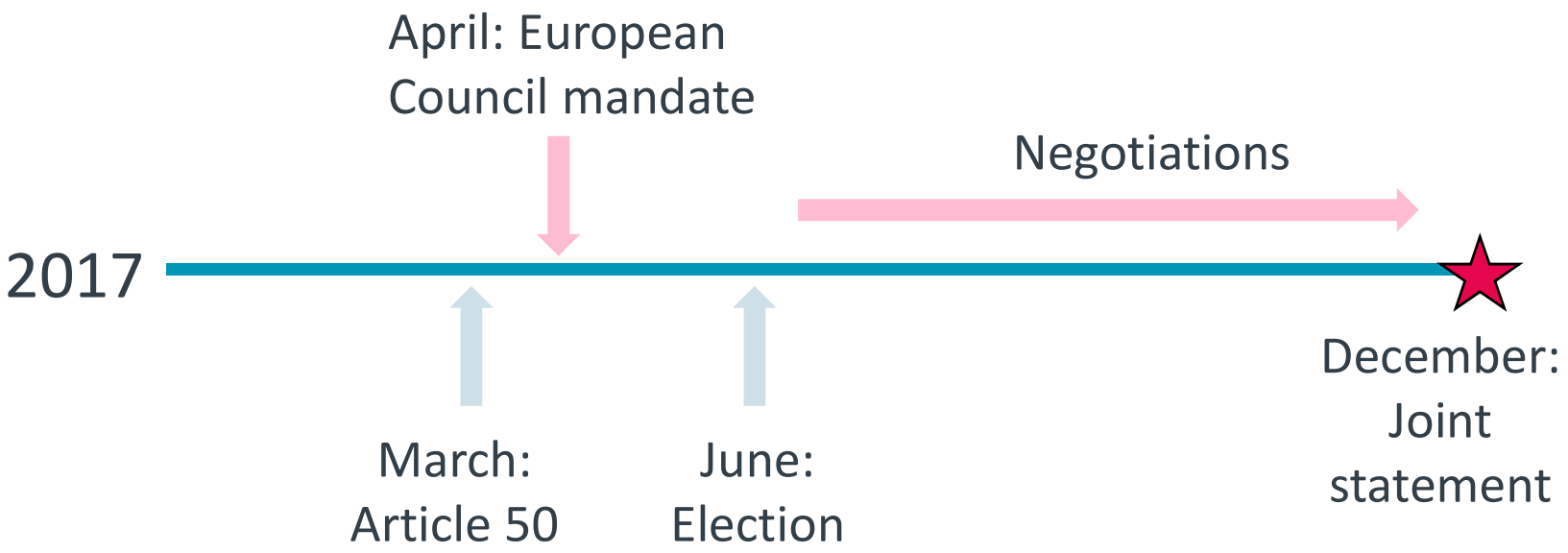
Timing is Crucial...

THE STORY SO FAR…



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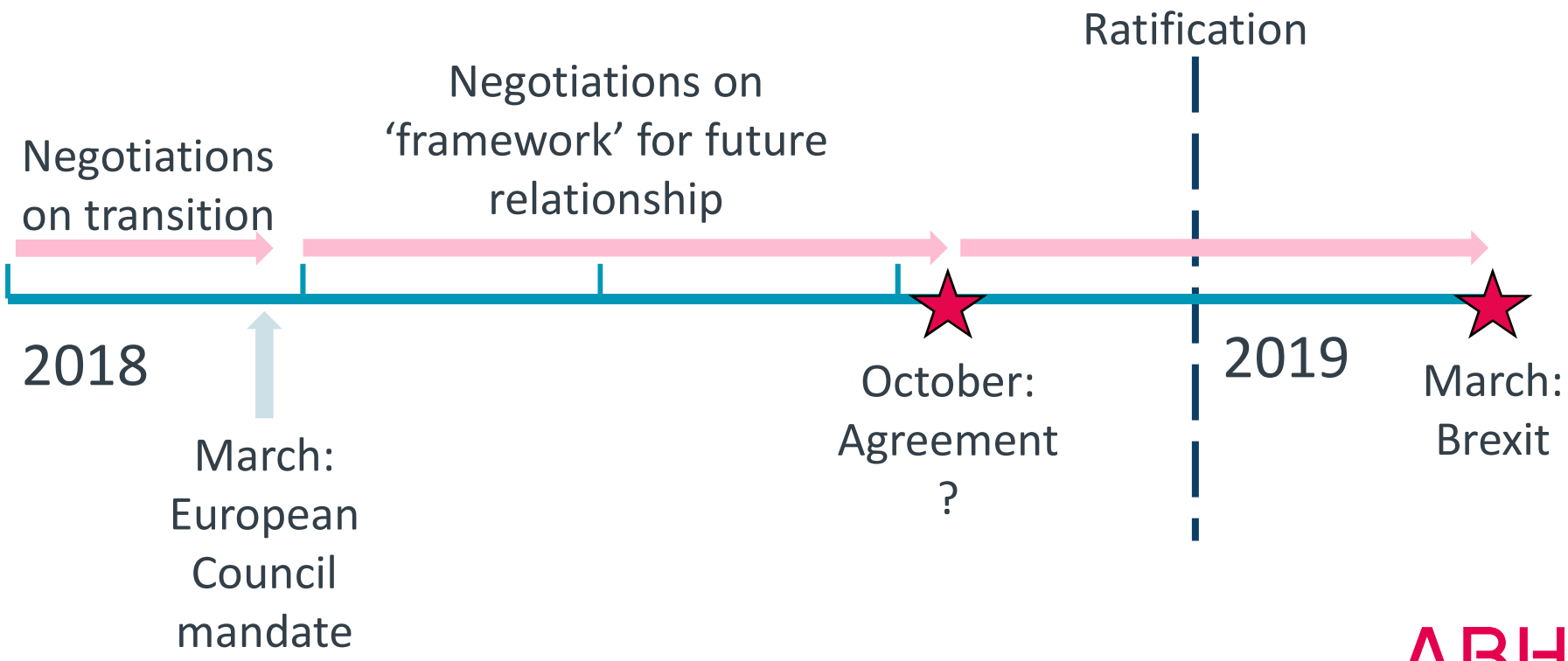

THE STORY SO FAR…

Negotiations and after March 2019?

- UK officially becomes 'a third country'
- MDR only partially implemented
- Future relationship negotiations begin in earnest
- Transition period – until Dec 2021
    - **MDR fully implemented**
    - **IVDR still undergoing transition**
    - **Legal standing of MDR**
- Role of UK during implementation period

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CHALLENGES

Working with Whitehall : Implementing Multiple Scenarios

NO DEAL	
What is needed?	By when?
Immigration system for all EU citizens	March 2019
Customs system for all EU imports and exports	
New regulators for current EU functions	
Agreements with third countries	

NEGOTIATED OUTCOME	
What is needed?	By when?
New immigration system – depending on deal	End of transition
New customs system – depending on deal	
New regulators – depending on deal	
Agreements with third countries	

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SO WHAT?

ABHI Key Considerations

- Regulatory alignment
- Movement of goods

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SO WHAT?

Regulatory Alignment: Concerns

- Will the EU Withdrawal Bill be enacted essentially in current form?
- Will there be mutual recognition with the EU?
- Will the Transition Agreement be agreed, or will the UK "crash out of the EU" (Hard Brexit?)
- Will the UK Government introduce laws bringing MDR/ IVDR into UK law?
- ……or will there be something different?

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SO WHAT?

Regulatory Alignment: Concerns

UK Law from 30 March 2019

EU law enacted as UK law (Directives):
Become "stand-alone" UK law:
MDD/ AIMD/ IVDMDD

EU law with direct effect (Regulations):
Become part of "stand-alone" UK law ONLY if both in force AND "applicable" at **29 March 2019**:

Most provisions of MDR and IVDR will not be part of UK Law on 30 March 2019

Transition

EU law will apply in UK until 31 December 2020

EU LAW

Gradual applicability of MDR and IVDR:

26 May 2020: MDR fully applicable

26 May 2022: IVDR fully applicable

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SO WHAT?

Regulatory Alignment: Will UK Government enact MDR and IVDR

For

1. "Close, warm relationship" = Mutual Recognition
2. MHRA instrumental in drafting
3. MDR/ IVDR represent the latest thinking on best practice
4. Access to other markets that recognise the CE mark

Against

1. Need to follow ECJ decisions?
2. c.60 sets of secondary legislation (UK no input to these)
3. Desire to be seen to have "sovereignty"

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Regulatory Base, post-March 2019

"[Highlighting] … the leading role played by the UK in the recent negotiations of new EU regulations for medical devices and in-vitro diagnostic medical devices. The UK has already welcomed the new requirements of these regulations to protect patients while encouraging innovation."

Lord O'Shaughnessy,

Parliamentary Under-Secretary of State, Health (September 2017)

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Regulatory Base, post-March 2019

"Elements of the new regulations have been applied directly in UK law since May [2017], meaning devices can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements.

As it stands, the EU (Withdrawal) Bill would maintain this position beyond March 2019."

Lord O'Shaughnessy,

Parliamentary Under-Secretary of State, Health (September 2017)

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Specific MDR Questions…

- Implementing and Delegated Acts
- European Court of Justice
- EUDAMED
- Notified Bodies
- Authorised Representatives
- Person Responsible for Regulatory Compliance
- Distribution Chains
- Post-Market Surveillance
- Allied Regulations

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Implementing and Delegated Acts;
Convergence vs. Divergence

- MDR identified for regulatory stability and certainty
- Implementing and Delegated Acts
  - **Regulatory Convergence or Divergence**
  - **How to deal with these 'post-Brexit'**
  - **MDD+**
  - **Acts or guidelines?**
- Input beyond March 2019 and the role of the MHRA

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European Court of Justice;

A hurdle too far?

- European Court held as ‘backstop’ to MDR issues, particularly those related to vigilance.
- What to include as part of transposition?
- Change of ‘backstop’?

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EUDAMED;

Public Health Risk?

- 'Go Live' date for several modules due just before May 2020
- Cliff-Edge scenario would mean EUDAMED not implemented
- Vigilance module;
    - **Major contributors are UK and Germany**
    - **Public Health issue if reporting diluted?**
- UK alternative?
- 'Pay-as-you-go' scenario?

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Notified Bodies;

Red Herring?

- Notified Bodies under considerable strain re. capacity and timings
- UK Notified Bodies working on Plan ‘B’
- Need for Notified Body to be EU domiciled
- Change in Notified Body number to be expected;
    - MDR
    - MDD
- Ensure dialogue, NOW!

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Authorised Representatives;

Plan for your EU Representative…

- MDR requires AR to be EU domiciled – will a Mutual Recognition Agreement allow for AR to be in the UK?
- Potentially requires;
    - New labelling
    - New contracts
    - Person Responsible for Regulatory Compliance
    - New PMS requirements
- Will UK require an 'Authorised Representative' to manage UK transposition of MDR?

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Person Responsible for Regulatory Compliance (PRRC);

- Authorised Representatives require the services of a PRRC;
- Duplication of roles
- Another question of ‘Mutual Recognition’
- Who will hold any Technical Files?

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Distribution Chains;

Product supply issues – Customs and Tariffs…

- Many ‘touch-points’ across Europe for manufacture and distribution of finished as well as in-process goods
- Customs points potentially as a ‘bottle neck’
- Ireland / Northern Ireland border
- Procedure Packs / Virtual Manufacturing
- New Technologies
- Prohibitive additional costs?

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Post-Market Surveillance;
Another red herring?

- PMS processes should not be affected?
- More difficult to obtain data from EUDAMED
- Allied to EUDAMED questions
- UK databases

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Allied Regulation;

Not just the MDR…

- Environmental considerations (should be included as part of the 'Withdrawl Bill';
  - REACH
  - WEEE
  - RoHS
- Other legislation will need consideration;
  - General Product Safety
  - Machinery
  - Etc.,
- Change control!?

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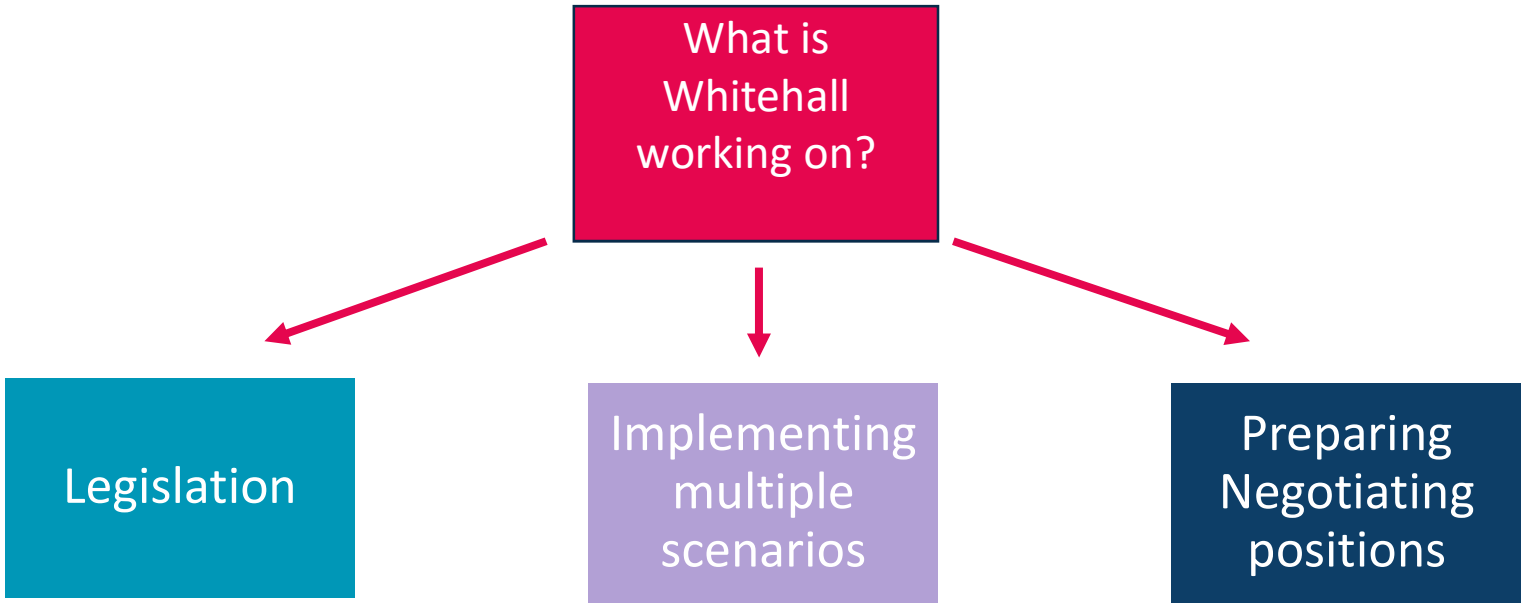
Challenges

Working with Whitehall



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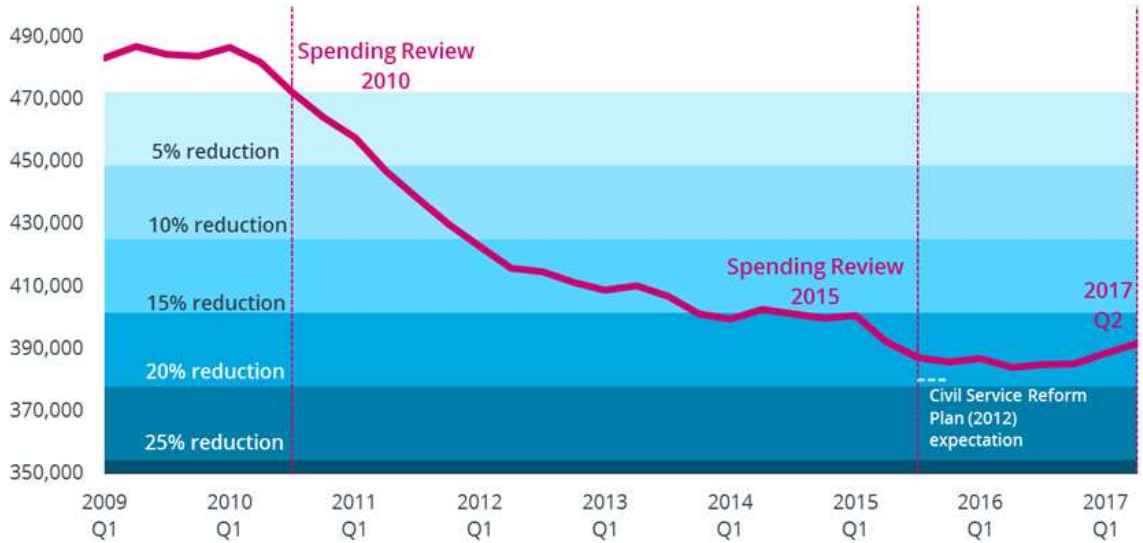
CHALLENGES

Working with Whitehall: Legislation

- Key piece of Brexit legislation: EU Withdrawal Bill
- Numerous other Brexit laws
- Huge volume of secondary Brexit legislation

All with the smallest civil service since WWII…



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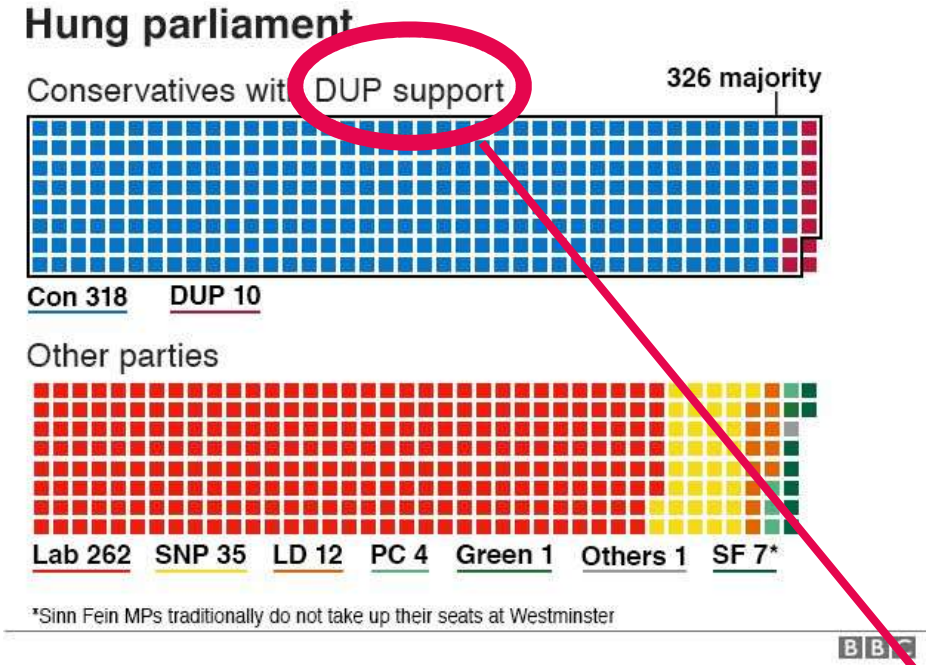
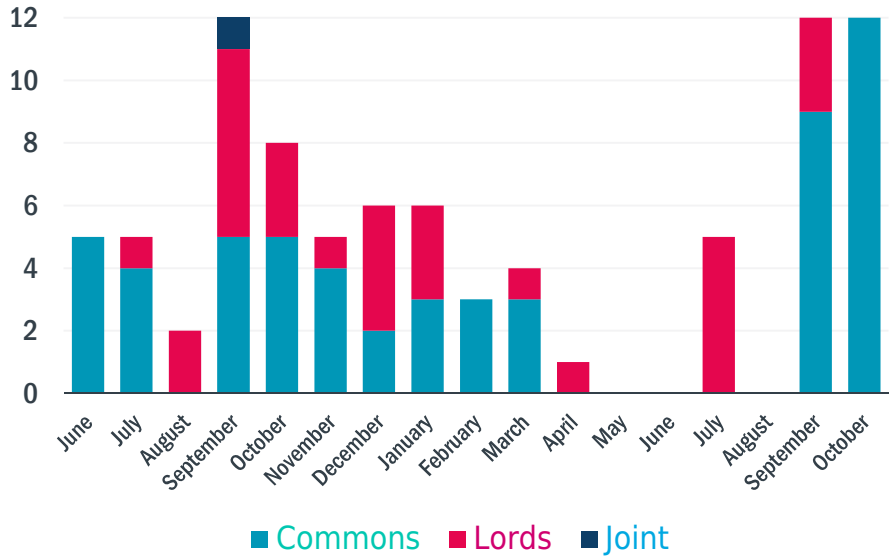
CHALLENGES

Working with Parliament…





The Irish challenge…

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Conclusion;

It's easy to say, "Don't panic…"

"A woman's guess is much more accurate than a man's certainty."
— Rudyard Kipling, Plain Tales from the Hills

"…but in this world nothing can be said to be certain, except death and taxes."
— Benjamin Franklin,

"I believe that we do not know anything for certain, but everything probably."
— Christiaan Huygens,

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