



Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human and veterinary medicinal products

Welcome and opening remarks

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United Kingdom under Article 50 TEU



European
Commission

Negotiations with the United Kingdom



UK's withdrawal from the EU

Main ongoing workstrands:

- Withdrawal agreement ("Article 50 agreement")
- "Transition period" (part of the "Article 50 agreement")
- "Future relationship"

Bottom-line: UK will be a "third country" on 30/3/19



Withdrawal agreement

- "Winding down" of EU membership
- Large parts agreed
- But critical points still open
- available here:
https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf

State of play – Withdrawal Agreement

Citizens' rights

- Protection of life choices for citizens arriving in host state until end of transition period
- Simple administrative procedures
- ECJ for citizens' rights

Financial settlement

- Financing of the whole MFF
- Mechanism for payment of liabilities (including pensions)
- ECJ for financial settlement

Transition

- Status quo – *minus institutions and decision-making*
- To last until end of 2020

Other separation issues

- Some progress: goods on the market, customs, EURATOM, civil law, public procurement etc.
- Main remaining issues: geographical indications, personal data, police and judicial cooperation

Governance

- Disagreement on dispute settlement

Ireland / Northern Ireland

- Agreement to address all issues
- UK recognises need for a legal "backstop" solution in Withdrawal Agreement
- Disagreement on the operative solution

"Transition period" (i)

- Full acquis applies to the UK
- Dynamic reference, i.e. including acquis that starts applying in the transition period
- No UK participation in EU institutions or EU bodies
- No UK participation in Member State meetings (subject to exceptions)
- No UK role as "leading authority"
- Full role of Court of Justice, Commission, Court of Auditors, etc.
- UK remains subject to obligations of international agreements concluded by the EU
- Financial settlement = rights and obligations of the MFF

"Transition period" (ii)

Duration: until 31 December 2020 (incl.)

Agreement still needs to be negotiated, agreed, and ratified

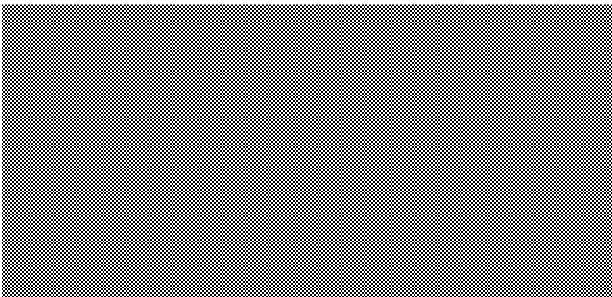
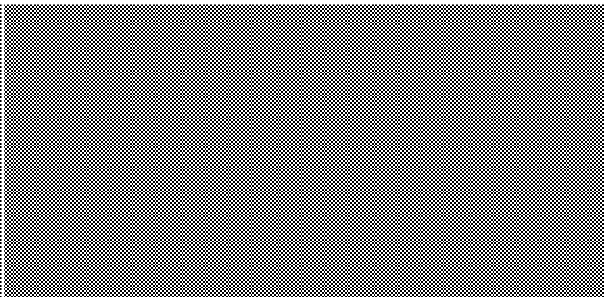
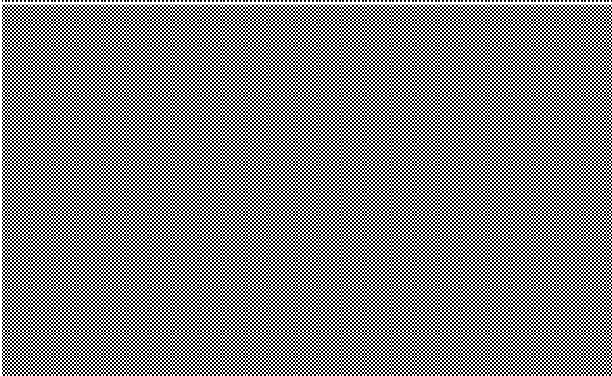

!! Do not rely on the "transition period" !!



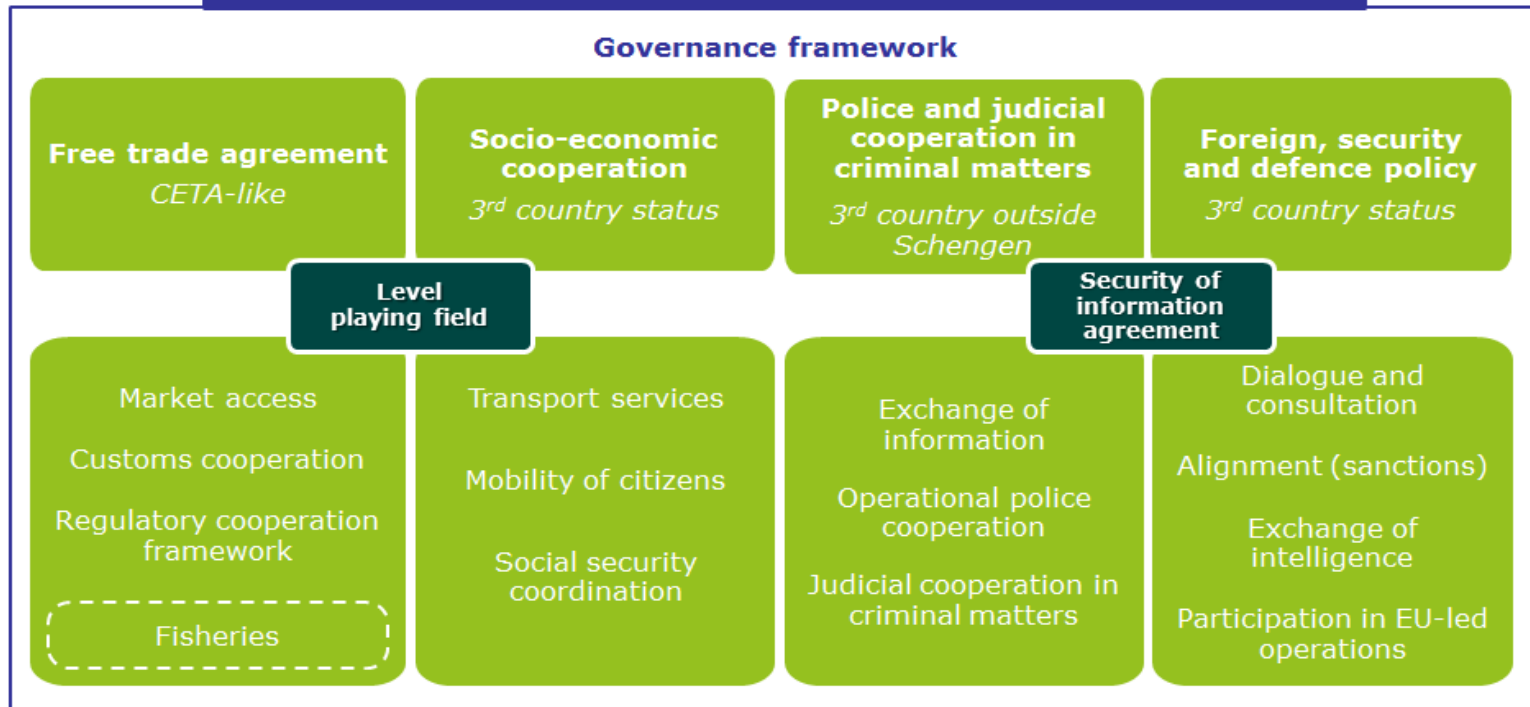
This means, that stakeholders have to prepare now

- Cf. Commission Communication of 19 July 2018
- "Brexit preparedness notices" - examples relevant for the pharmaceutical industry:
 - Pharmaceuticals (REV1 of 23/02/18; REV3 of 19/06/18) and clinical trials (6/09/18)
 - Medical devices ("industrial products") (10/01/18)
 - Customs (30/01/18), import/export licences (25/01/18) and VAT (11/09/18)
 - Trademarks (1/12/17) and IP enforcement by customs (4/06/18)
 - Personal data protection (9/01/18)
 - Professional qualifications (21/06/18)

International agreements of the EU

	Bilateral agreements	Multilateral agreements
EU-only		
Mixed		

EU/UK Possible Framework for the Future Partnership Discussions



EU legal basis for 3rd countries in EU programmes (*)
e.g. Horizon Europe

EU autonomous measures
e.g. 3rd country equivalences in financial services, adequacy decision on data protection

(*) To be discussed in the Multiannual Financial Framework context

Brexit – Next steps

