What are the Regulatory Implications of BREXIT?

Does this impact the “Seismic” concurrent EU regulatory changes?

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Key Facts Expectations & Assumptions

- Consensus data indicates that circa 45% of all Medical Devices CE marked in Europe utilize UK NB for their conformity assessment requirements

- It is estimated that 70% of Non-EU Based Manufacturers USE UK Notified Body Services

- There is an acute need to maintain Patient Access to life-saving and life-enhancing technologies

- Well recognised mechanisms exist for non-EU Member states to be part of the EU regulatory system either as part of EFTA/EEA or through MRA (e.g. Norway/ Switzerland and Australia)

- BSI is in frequent contact with HM Government (BEIS/DEXEU and DIT) and kept well informed. This reinforces our expectation which remains that suitable mechanisms will be found to provide continuity of access to the wider European Union trade area after the transition period
Treaty on the Functioning of the European Union (“TFEU”)

Key Aspects:

- Firstly this is a draft and could be rescinded in a non-negotiated outcome!
- The “TFEU” extends current regulatory arrangements until December 2020
- The “TFEU” is unclear (in that it does not state) as to what the Status of CE certification would be post-2020
- However, our discussions with HM Government indicate that there is no desire to disrupt access to vital goods and services (both by HMG and the EU Commission /Parliament) quite the converse, there is a consensus on the importance of maintaining functioning markets
- Expectation remains of an ongoing participation within the existing EU MDR & IVDR regulatory system for Medical Devices
Impact of Models on Movement of Goods

- **Single market**
  - Goods in free circulation move freely within single market

- **Customs Union**
  - Goods in free circulation are not subject to customs duties when moving within customs union, but:
    - Customs declarations required (?) and import VAT payable
    - Possible simplifications?
    - UK imports benefit from EU FTAs but UK exports do not

- **FTA**
  - Preferential duty rates* only available for goods which meet origin rules
  - Customs declarations required and import VAT payable
  - Possible simplifications?
  - UK trade does not benefit from EU FTAs

- **Fallback (WTO)**
  - No preferential treatment*
  - Customs declarations required and import VAT payable
  - UK trade does not benefit from EU FTAs

* only of concern for dutiable products

https://www.gov.uk/guidance/rules-of-origin
Medical Devices: Pre-Brexit

Manufacture in UK
Supply of materials/components from the UK

NO DUTY; NO IMPORT VAT; NO BORDER CONTROL

Manufacture in EU
Supply of materials/components from the EU
Medical Devices: Post-Brexit – FTA Model

- Manufacture in UK
- Export from EU and import into free circulation in UK

NO DUTY IF:
(i) PRODUCT IS DUTY FREE;
OR
(ii) ROO IS MET
BUT IMPORT VAT

- Export from UK and import into free circulation in EU
- Manufacture in EU
Non-Negotiated (or Hard) BREXIT

Medical Devices: Post-Brexit – WTO Model

Manufacture in UK

Export from EU and import into free circulation in UK

* unless product is duty free

Export from UK and import into free circulation in EU

Manufacture in EU
If Required Full Migration to Our Netherlands NB Within Target Timelines
90/385/EEC
93/42/EEC
98/79/EC

Initial Designation
MDD & AIMDD:
- 07 Feb 2017 Application
- 01 March 2017 Completeness check
- Full Application 16 June 2017
- 16 June 2017 Inc. IVD Application
MDD & AIMDD:

11-15 September 2017 Joint Audit
- 20 November 2017 JAT Report
- March 2018 Verification CAPA plan
- **08-10 May 2018 Follow up JAT**
- Responding with CAPA Plan
- CA & Des. Auth. (NL MOH). Recommendation
- EU Com/Mem. State CA Comments
  (1 month)
- **Expected Designation Q3 2018**
MDD, AIMDD and IVDD

MD & AIMD:
- Applications Q3 2018
- Certificates Q3 2018

IVDD:
- 18/19 June 2018 IGJ Audit
- Designation late 2018
Manufacturers can apply for a second certificate or move their certificate in future.

**A Great Team Effort ...**

BSI will provide a more comprehensive client communication on this in the coming weeks including timelines.
EU/2017/745 MD Regulation
EU/2017/746 IVD Regulation

Initial Designation
Maintaining Designation
MDR & IVDR:
- 27 & 28 Nov Applications
- 28 Dec. Completeness
- JA Expected 09/18 MDR &
- Q4 2018 IVDR
  • Aiming for Designation H1 2019
UK to NL Migration
BSI Conformity Assessment

- Quality System Audits
- Unannounced Audits
- Microbiology & Sterilisation Audits
- Technical Documentation Reviews

Identical Competence
Identical Processes
Contracts and Certificates
Information for Users

SPR#23

(e) medicine, human, animal
(f) CMR + ED >0.1%
(j) reprocessing cycles
(p) custom made
(q) clinical investigation
(r) quantity of constituents – achieving principal intended action

*Article 20

“In the event of a merger, it is for the newly-merged NB to decide on its identity/brand, and to choose which if the two NB numbers it will retain.”

“This is why, to avoid excessive costs, we have suggested in the past that the listing in NANDO ... as NBXXXX (also ex NB YYYY) so that the reference of the old NB can still be found.”

“...manufacturers don’t need to relabel products which have already been placed on the market to refer to the new NB number, since the old number can still be traced in NANDO.”
MDR Transition (Article 120)

- **Entry into Force (OJEC + 20 days)** (25 May 2017)
- **05 May 2017 Adoption of MDR**
- **Transition period 3 years**
- **Date of Application (26 May 2020)**
- **MDD/AIMD certificate validity (4 years)**
- **Annex IV certificates expire (27 May 2022)**
- **Last MDD/AIMD certificates expire (27 May 2024)**
- **27 May 2025 No more « placing on the market » of devices covered by MDD/AIMD certificates**
- **MDD/AIMD certificates (max 5-year expiry from issue/renewal date)**
- **No more « placing on the market » of devices covered by MDD/AIMD certificates**
- **NBs designation under MDR**
Do Not Leave Your Regulatory Transition Plan Too Late

(Irrespective of BREXIT)

- Deadlines & Timelines are Pressing
- The System Lacks Capacity
- Less than 50% MD NB have indicated publicly they are going to apply for the MDR
- Less for the IVDR

If you align expectations with reality, you will never be disappointed.

Terrell Owens (US athlete and NFL Player)