Technical expert seminar (EU27) on medical devices in relation to the withdrawal of the United Kingdom from the EU

15 February 2019
Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs

UK's withdrawal from the EU

As of **30 March 2019, 00:00h** (CET), in the absence of a ratified withdrawal agreement:

- UK becomes a third country
- MD coming from the UK to be considered as **import**
- **MD placed on the *UK market* prior to the withdrawal date, but made available (e.g. sold) on the *EU27 market* as of the withdrawal date => placing on the *Union (EU27)* market occurs as of the withdrawal date**
- UK conformity assessment bodies **no longer 'Notified Bodies'** in NANDO

Placing on the EU27 market

Art.1(2)(h) MDD

Art. 2 MDR, points 27-28

- '**making available on the market**' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- '**placing on the market**' means the first making available of a device, other than an investigational device, on the Union market;

Placing on the EU27 market

Placing on the market:

- relates to each **individual unit**, even if manufactured in series
- first making available on the EU27 market
  - does **not** require physical **delivery** of the device
  - **but** requires the **manufacturing** stage to be **completed**
  - for imported MD: section 2.4 of the Blue Guide:

    http://ec.europa.eu/DocsRoom/documents/18027

    (in particular placing on the market *vs.* release for free circulation by customs)

Authorised Representative - appointment

- UK manufacturer => requires an EU27 AR
- Can UK manufacturer appoint EU27 AR prior to the withdrawal date? The question arises because until the withdrawal date UK is EU28 MS!

  => The appointment of AR can take place before the withdrawal date, but should take effect as of the withdrawal date ('conditional appointment')
- UK AR appointed by 3rd country manufacturer for the EU => requires re-location to EU27 / appointment of a new AR in EU27

Authorised Representative

- information update

- Update of the **Declaration of Conformity** and the **certificate**, if AR has been indicated in those documents
- Update of the **competent authority** of MS where AR has a registered place of business
  - MDD Article 14(1) and (2) (Class I + custom made)
  - AIMD Article 10a(2) the second subparagraph (custom made)
  - IVDD Article 10(3)
- Update in **Eudamed** (Eudamed Decision C(2010) 2363), where appropriate

Authorised Representative

- information supplied with the device

- MD placed on the EU27 market ***prior*** to the withdrawal date => **no changes**
- MD placed on the EU27 market ***as of*** the withdrawal date:
  - MDD => EU27 AR needs to be indicated on the label, or the outer packaging, or instructions for use (Annex I ER 13(3)(a))
  - AIMD => EU27 AR needs to be indicated on the sales packaging (Annex I ER 14(2))
  - IVDD => EU27 AR needs to be indicated on the label, or the outer packaging, or instructions for use (Annex I ER 8(4)(a))

Importers / distributors

- Current EU27 distributors become EU27 **importers** for devices they place on EU27 market that they have purchased from a UK manufacturer
- The same applies for devices imported from third countries and first placed on the UK market

Transfer of certificates and change of NB number

- As of withdrawal date, manufacturer must have a certificate of an EU27 NB to place devices on EU27 market
  - **transfer of the existing certificate** from UK NB to EU27 NB

  or
  - a **new certificate** from an EU27 NB
- ***CE marking - NB identification number***
  - devices placed on the EU27 market or manufactured ***prior*** to the certificate transfer => **no change, provided that the product documentation is in order**
  - devices manufactured **after** the certificate transfer => **change**

Competent authorities' advice to the operators (1/2)

Competent authorities to raise awareness among national stakeholders about regulatory consequences for medical devices placed on the EU27 market prior to or as of the withdrawal date

- **Devices manufactured in the UK or imported into the UK from third countries, with an intention of further distribution in EU27**:
  - **Economic operators** to**:**
    - Review the status of key actors in the regulatory chain to see if changes are needed (e.g. appointment of EU27 AR; EU27 distributor becomes an importer)
    - Update competent authorities where needed (e.g. any national databases)
    - For individual items/batches, keep documentation which indicates the date of their placing on EU27 market

Competent authorities' advice to the operators (2/2)

- **Devices certified by UK NBs**:
  - **Economic operators** to:
    - Transfer the certificates to EU27 NB or seek new certificates from EU27 NB
    - Update product documentation (Declaration of Conformity and NB Certificate) with new NB details, change NB number on product manuactured after certificate transfer or new certificate issued
    - For individual items/batches manufactured with a UK NB number on them, keep documentation which indicates the date of manufacture

Re-location of UK Notified Bodies to EU27

- **NB 0086 – BSI Assurance UK Ltd**: 2017/745, 90/385, 93/42, 98/79
- **NB 0088 - LLOYD'S REGISTER QUALITY ASSURANCE LTD**: 93/42, 98/79
- **NB 0120 - SGS United Kingdom Limited**: 93/42, 98/79
- **NB 0473 – AMTAC CERTIFICATION SERVICES LTD**: withdrawn (previously: 93/42, 98/79)
- **NB 0843 – UL INTERNATIONAL (UK) LTD**: 93/42 (re-designation under Reg 920/2013 not finalised), 98/79
  - **Following the withdrawal date, UK NBs will lose their status and will be removed from NANDO**
  - **Relocation of activities to EU27 as an option**

Guidance

- Brexit negotiations and preparedness - general website

https://ec.europa.eu/info/brexit_en

- Brexit – general website with guidance to stakeholders on impact in the field of industrial products

https://ec.europa.eu/growth/content/brexit-%E2%80%93-guidance-stakeholders-impact-field-industrial-products_en

- Notice to stakeholders - 22/1/2018 – Withdrawal of the UK and EU rules in the field of industrial products

https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf

- Industrial products – Questions and Answers – 1/2/2019

https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf