Notified Bodies (NBs) – A Key Pillar of the Medical Technology Regulatory System

Notified Bodies are responsible for assessing medical devices (MDs) and *in vitro* diagnostics (IVDs). They are an indispensable part of the regulatory system since they grant a CE mark to each device before it can be placed in the EU market.

Notified Bodies are undergoing a significant revamp in order to comply with their greater obligations according to the new Medical Device and In Vitro Diagnostic Regulations.

**Key facts about Notified Bodies**

- **Independent**
- **Impartial**
- **Designated and supervised by National Authorities**
- **Grant EU-wide product approval**
- **Public or private**
- **Identified by a 4-digit number, placed with the CE mark**

**How many Notified Bodies (re-)certify MDs and IVDs?***

<table>
<thead>
<tr>
<th>Year</th>
<th>NBs</th>
<th>Details</th>
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<tbody>
<tr>
<td>2012</td>
<td>87</td>
<td>Tightened controls and joint audits for NBs due to Dalli Plan</td>
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<tr>
<td>2019</td>
<td>59</td>
<td>36 NBs can assess MDs, of these: 13 can also assess active implantable MDs 22 can also assess IVDs 1 NB assesses IVDs only</td>
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<tr>
<td>2020</td>
<td>?</td>
<td>Countries can have a different amount of NBs: none, one or several</td>
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*EC NANDO database
Designation of All Notified Bodies (NBs) Under the New Regulations

All existing and new Notified Bodies need to be designated to prove their competence in assessing products and quality systems under the increased requirements of the new regulations. This designation process includes four steps and is expected to take on average 18 months per Notified Body (source: NBOG).

1. Pre-assessment & off-site activities
2. On-site assessment activities & CAPA (Plan For Corrective And Preventive Actions)
3. Post-assessment activities
4. Notification in EC NANDO database

The designation procedure started on 26 November 2017. To date only one Notified Body has been designated under the MDR (in the UK), none under the IVDR. Further designations are expected in Q2/2019. Potentially only 12 Notified Bodies will be available by Q4/2019.

The Notified Body system will face a crunch time

- The new regulations came into force on 26 May 2017; the dates of application are 26 May 2020 for MDs and 26 May 2022 for IVDs.
- From the dates of application, only NBs that are designated for the new regulations can assess and (re-)certify products.
- Before that date, ~314,000 of 500,000 MDs and ~35,000 of 40,000 IVDs currently CE marked need to be (re-)certified to remain on the EU market. There are approximately 55,000 certificates issued under the old Directives.
- The ‘grace period’ does not solve the excessive work load that NBs face before May 2020 because: – many products are not eligible for the ‘grace period’; – eligible products would still need to be re-certified by May 2020.

What is the ‘grace period’? It allows for certain devices to be placed on the market with a valid certificate based on the IVD/AIMD/MD Directives. This period starts from the date of application of the new Regulations to until 26 May 2024.
A Massive Increase in Notified Body (NB) Workload

Today
With 30% fewer NBs and tighter controls than in 2012, many NBs are already overstretched with (re-)certifications under the current IVD/AIMD/MD Directives, triggering delays in approval of products.

Tomorrow
NBs will have to follow additional and more stringent requirements under the new regulations (e.g. on clinical and post-market surveillance aspects). This will have further impact on the available time to review products.

Three main challenges

Lack of time
NBs have insufficient time between their designation and the dates of application of the new regulations to perform the required (re-)certification of products including:
- All CE marked products that are already on the market (re-certification);
- Products that will have Notified Bodies oversight for the first time (certification):
  - 85% of all IVDs;
  - Certain MD categories such as reusable surgical instruments;
- New and innovative products certification.

Lack of capacity
NBs need more capacity to absorb higher amounts of work. The current capacity challenge is further expanded because:
- Only one of the 59 existing NBs has been designated under MDR (as of May 2019);
- Not all 59 NBs will apply and succeed with the designation under the new Regulations;
- Brexit risks to decrease the certification capacity that is currently carried out by UK Notified Bodies;
- NBs must continue to certify products while being (re-)designated to the new regulations.

Lack of available experts
NBs are facing challenges in finding, hiring and training staff to address the requirements of the new regulations:
- Additional expertise to check products against the new requirements is not sufficiently available;
- In-house staff has one to two years learning curve to be fully operational.

Too few appropriately staffed Notified Bodies will be available early enough to absorb the workload prior to the dates of application of the new regulations.
Foreseen Consequences

For manufacturers

• Impossibility today to file products for certification under the regulations until Notified Bodies are available;
• Lack of business predictability due to lack of clarity about which NB will have capacity at what point in time and for which product categories;
• Increased waiting time to obtain CE marking;
• Increased vulnerability and uncertainty for SMEs, which represent 95% of the sector;
• Disruption in the supply chain.

For patients, healthcare professionals, hospitals and laboratories

High risk of delay or discontinuation of access to medical technology products.

For the EU as a whole

Potential loss of competitiveness against other global constituencies (US, China, etc).