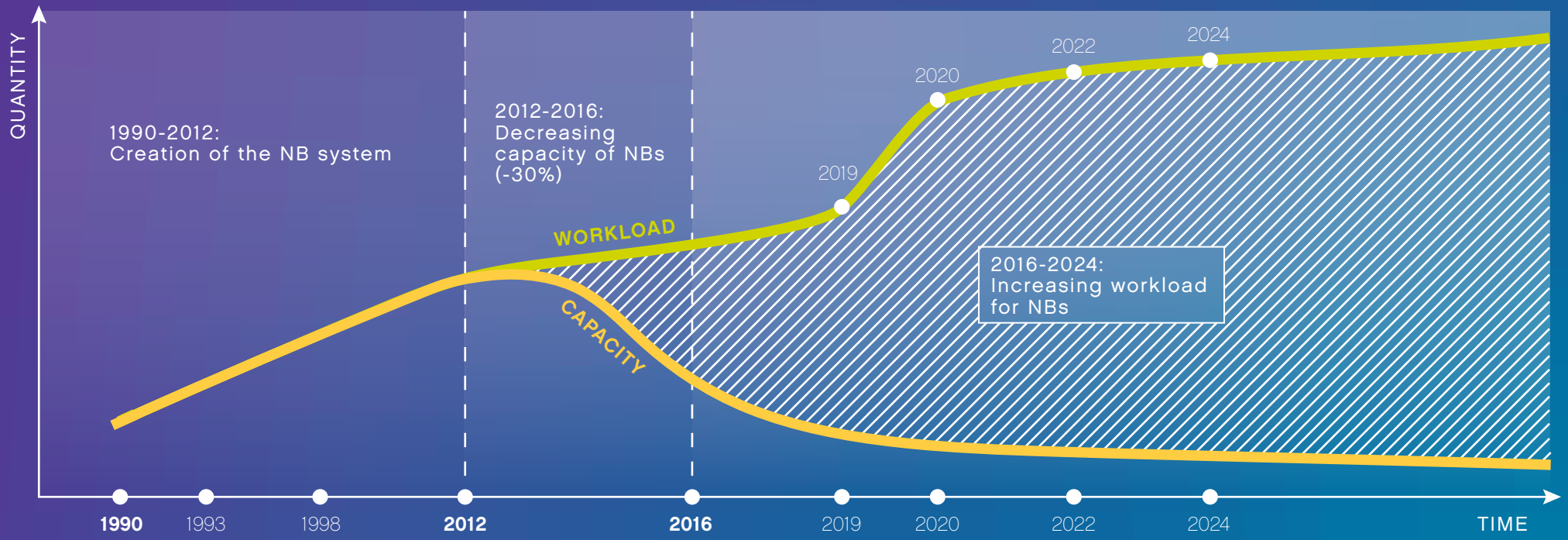
New Medical Technology Regulatory Systems –
An Urgent Need to Close the Gap

The involvement of Notified Bodies (NBs) in certifying medical technologies has evolved over the years and it is currently experiencing a significant revamp with the new CE Marking Regulations adopted in 2017.

This leads to a situation where less and less NBs have to manage more extensive work.

The gap between Notified Body's capacity and the existing workload increases significantly. This needs to be urgently addressed by policymakers at EU level in order to guarantee a smooth continuation of supply of medical technologies to patients and healthcare systems.

NB Capacity vs Workload Over the Years



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1990-2012: Creation of the NB system

EU legislation for medical technologies dates back to the 1990s*: It required the creation of independent NBs to audit and certify medical technologies as a prerequisite to put them on the market.

The number of NBs increased due to the accession of new Member States to the EU.

NBs' capacity was rarely an issue: NBs could cover the ever-growing and more diverse medical technology products.

**Three EU Directives: Active Implantable Medical Devices Directive (AIMDD - 1990); Medical Devices Directive (MDD - 1993); In Vitro Diagnostic Medical Devices Directive (IVDD - 1998)*

2012-2016: Decreasing capacity of NBs

The **'Joint Plan for Immediate Actions' of EU Member States and European Commission** resulted in tighter designation and control measures for NBs. This led to a ~30% decrease in the number of NBs:

- Some lost their designation to the Directives*
- Some lost their right to assess certain products
- Others voluntarily withdrew from the sector

Consequences:

- Increased NBs quality; but
- Remaining NBs had to absorb 'orphaned' products

  → Capacity problems of the NB system overall arose to certify and monitor more than ½ million existing and new products on the EU market.

2016-2024 and beyond: Increasing workload for NBs

Since 2016, NBs have had more work to do simultaneously:

- Certify quality systems of all manufacturers against updated ISO 13485:2016
- Certify quality systems for importers and distributors as of 2020 (MDs)/2022 (IVDs)
- Seek their own designation to the new EU CE Marking Regulations (since Nov 2017)
- Recertify existing and legacy products under the current EU Directives (huge spike expected from 2019)
- Start certifying all products on the market to the new Regulations
- Recruit and train new experts to cover 85% of IVDs certified by NBs for the first time as of 2022
- Post (hard) Brexit: absorb 30-40% of certificates issued and surveilled by UK NBs

Consequences

of growing lack of overall NB capacity in the EU to (re-)certify products

1. Threat to industry's ability to supply medical technologies to patients and healthcare systems
2. Loss of business predictability, thus higher market volatility and loss of European competitiveness against other global markets
3. Increased vulnerability and uncertainty for SMEs, which represent 95% of the medical technology sector
4. Delayed access to innovative technologies for patients and healthcare systems

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