(Re-)Designation process for notified bodies means bottlenecks for medical devices manufacturers

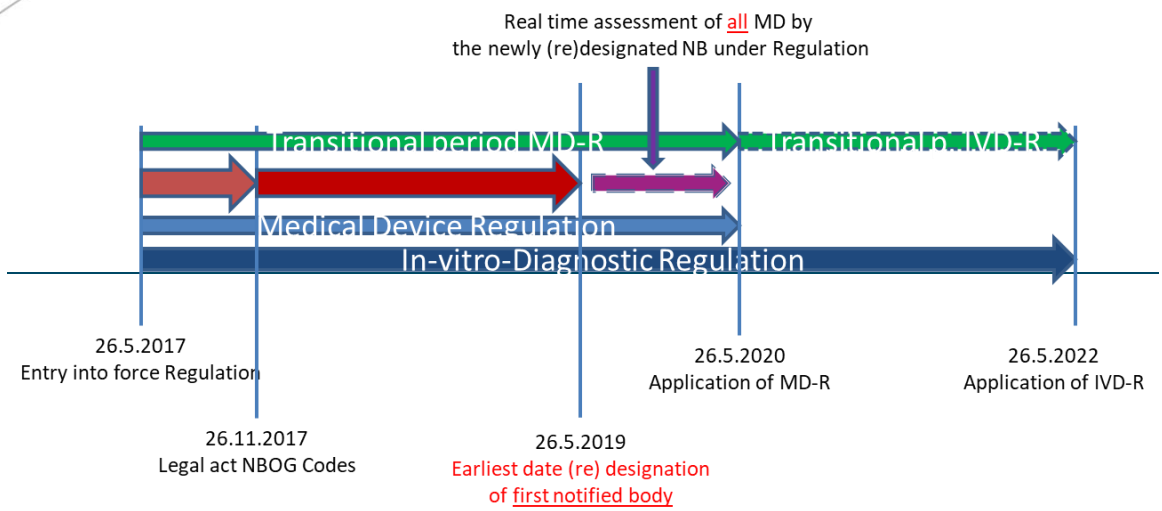
The new Medical Devices Regulation (MDR) and the new In-vitro Diagnostic Medical Devices Regulation (IVDR) entered into force on 26 May 2017. These new pieces of legislation decisively extend the requirements to manufacturers and also to notified bodies. With the new classification rules, the number of products falling under the control of notified bodies increases significantly, too. Moreover, the scope of controlled fields – from pre- to post-market – also widens immensely. Therefore, it is of utmost importance to (re-)designate the notified bodies as early as possible, in order to have sufficient numbers of notified bodies available when the Regulations start to apply in 2020 and 2022, respectively: for assessing products before manufacturers can place them on the market.

The AG MPG (Working Group of Industrial Associations for the German Medical Devices Act) is highly critical of the following points:

Critical components regarding timelines:

- Before notified bodies can apply for (re-)designation under the new Regulations, the Commission needs to establish the various fields of competence (NBOG codes). These fields of competence determine the scope of the work where the individual notified bodies can be active.
- The Regulations provide for publishing NBOG codes within the first half-year after entry into force (i.e. by 26 November 2017).
- Once this task has been completed, notified bodies can apply for the respective fields of competence and be (re-)designated. The (re-)designation process is described in the Regulations and will be carried out similarly to the description in the NBOG paper [NBOG BPG 2016-1 (Re-)designation of notified bodies: Process for joint assessments].
- Thus, the first notified bodies will be (re-)designated at the earliest 1.5 years after publication of the NBOG codes. But this is only possible where there are no queries or demands for further documentation/testing from the competent authorities during the process – so that the above describes an ideal case of the (re-)designation process; in our view, this is hardly realistic and feasible.
- Consequently, the first notified bodies would be able to start working at the earliest two years after entry into force of the MD / IVD Regulation (1/2 year establishing NBOG codes + 1 ½ years until the first (re-)designation). **Having discussed this matter with the relevant stakeholders, the associations are expecting a rather longer timeline of at least 2.5 years.** With transitional periods of 3 years for medical devices and 5 years for in-vitro diagnostic medical devices this is much too late for having (re-)designated a sufficient number of notified bodies prior to the date of application of the Regulations.
- The joint assessment process – which involves the Commission, the supervising Competent Authority of the Member State where the body to be (re-)notified has its headquarter and at least 3 further supervising Competent Authorities of other Member States – is likely to allow a maximum of 10 (re-)designation processes per annum for notified bodies. With currently over 50 notified bodies in Europe, this would mean that at least 5 years will be needed to re-designate all notified bodies. This is too long with transitional periods of 3 and 5 years for manufacturers!

In this figure we show the ideal timeline for the (re-)designation of the first notified body:



Critical components regarding amounts of products and numbers of notified bodies:

Most manufacturers (over 80%) in the MD/IVD sector are small and medium-sized enterprises (SMEs). The new Regulations bring fundamental changes in the regulatory sector for these businesses.

- On the European market, there are currently approximately 40,000 IVD products and 22 notified bodies designated for IVDs. They control less than 15% of these diagnostic products (6,000 tests). According to the Regulation, over 85% of these products will fall under controlling by notified bodies, corresponding to a share of at least 34,000 products. This means that the number of products alone has at least quintupled.
- It will be extremely difficult for those SMEs which have so far not been subject to control by notified bodies, to find a notified body in order to keep their products on the market. For products currently in Class I which will be up-classified in the future (e.g. software, reusable Class I instrument, the majority of IVDs, as well as medical devices, including dentistry and ophthalmology), an extension of the transition period based on old certificates with 4 years (MDR) or 2 years (IVDR) is not possible due to the previous self-certification.
- Moreover, there are stricter requirements in the control of manufacturers by notified bodies, both in pre-market and post-market. There is a comparable increase in the assessment workload for the MD sector. Thus the Notified Bodies are confronted not only with a quintuplication of the product quantity, but also at least with a doubling of their efforts in inspections and the assessment of the products.
- Compared to IVDs, the range of other medical devices (for example medical devices, implants, substance based medical devices, software, etc.) is very heterogeneous. For this reason only estimations of the additional workload resulting from the new requirements, which are significant, are available for this purpose.

Conclusion:

The AG MPG asks the national and European legislators to see to a faster process for the (re-)designation of notified bodies, so that new products can be placed on the market without delay and existing and well-established products remain available for patients. The legislator is called upon to bring the bottleneck in the (re-)designation of notified bodies in such a shape that enough time is given for manufacturers to have their products tested and certified by notified bodies. The industry associations are looking forward to the opportunity to offer their support.