Editor:Team-NB	Adoption date : 25/11/2020	Version 1
The European Association Medical Devices - Notified Bodies	**Team-NB Position Paper**	

Team-NB consideration paper on IVDR Date of Application

Background Introduction

The Date of Application (DoA) of Regulation EU 2017/746 on in vitro diagnostic (IVD) medical devices (IVDR) is currently set to be the 26/05/2022. According to Article 110, devices with a valid IVDD certificate may be placed on the market until 26 May 2024 (grace period).

This consideration paper aims to identify some key impacts on the current situation for the IVD medical device sector in the EU, and then describe some key considerations we as Notified Bodies want to highlight for any Commission decision making concerning the IVDR Date of Application.

Impact of the new classification system and conformity assessment requirements

The IVDR introduces significant changes in the regulatory requirements for IVDs including new classification rules and reinforced conformity assessment procedures. These changes will lead to a significantly increased number of IVDs requiring Notified Body assessment prior to CE marking: a study[1] conducted by the Dutch National Institute for Public Health and the Environment on the IVDs currently present on the Dutch market concluded that, under the current Directive, only 7% of the IVDs require a Notified Body assessment, while this percentage is increasing to 84% under the IVDR.

The same study estimated that applying IVDR classification rules, 1.5% of all devices would be Class D, 31,0% Class C, 51,7% Class B and 15.9% Class A.

Impact of Covid-19

All stakeholders' activities were significantly impacted by the COVID 19 outbreak. For Notified Bodies, the current impossibility to perform initial IVDR on-site audits is causing delays in the completion of the conformity assessment processes.

Notified Bodies position regarding the current IVDR Date of Application

Notified Bodies would support maintain the current Date of Application if the following conditions are met by the end of 2020:

1. The tools necessary to perform conformity assessments (e.g. CS published, EURL progressing according to plan, Expert Panels in place, relevant MDCG guidance documents including, but not limited to Classification, Performance Evaluation and explanatory note on IVDR codes guidance documents published) are available and ready for use

1 The impact of the new European IVD classification rules on the notified body involvement; a study on the IVDs registered in the Netherlands RIVM Letter report 2018-0082 A. van Drongelen et al.

2. At least 50% of the currently existing 22 Notified Bodies are designated under the IVDR: currently 4 NBs are designated under IVDR, however there will be only 3 after 31 December 2020 due to Brexit, unless additional NB are designated

These conditions would allow Notified Bodies to dedicate 2021 to the completion of conformity assessment processes. Completion of conformity assessments will remain a challenge whilst the Covid-19 pandemic remains, as there is a barrier to on-site initial QMS audits. This factor in itself may prevent all self-declared IVDD devices receiving certification by 26 May 2022.

If these conditions cannot be met, Notified Bodies recommend a decision regarding the DoA is taken by the end of 2020 at the very latest to minimise the impact on the IVD market and stakeholders

Assessment of alternate options: enlargement of the grace period

The small percentage of IVDs currently subject to Notified Body assessment significantly limits the impact of the grace period as currently set.

If the conditions above cannot be met, a possible alternative solution would be the enlargement of the grace period to include moderate/low risk devices (class B) and low risk devices (A sterile).

As discussed in the background section above, according to the 2018 report of the Dutch National Institute for Public Health and the Environment, class B devices represent >50% of the devices present on the market. Class A devices, including both sterile and non-sterile devices, would represent about 15 % of the devices available on the market.

This option would allow all stakeholders to focus on the timely implementation of the IVDR for high and medium risk devices in particular, for those devices that are classified as self-declared under the IVDD, but will be classified as class C or D under the IVDR.

This option could be implemented via a Corrigendum of the IVDR similarly to the approach taken for class I medical device under the MDR.

This solution presents two potential challenges:

1) The correct classification of the devices: While a rule based classification system is already applied under the MDD for Medical Devices, this system represents one of the fundamental changes introduced by the IVDR for IVDs. It is therefore necessary to ensure a detailed classification guidance is available to all stakeholders to facilitate the correct classification of devices
2) The tools (e.g. EU Reference Laboratories, Common Specifications) required for class D devices, would need to be ready well in advance of May 2022 to allow the completion of conformity assessments of those devices that are self-declared under the IVDD, but are being up-classified to class D under the IVDR. It should be noted that the exact number of devices falling in this category is currently unknown.

Assessment of alternate options: Postponement of the Date of Application of the IVDR

Following the challenges caused by the COVID-19 pandemic, the Date of Application of the MDR has been delayed to 26 May 2021, having the time gap between the Date of Application of the two Regulations and keeping the focus of all stakeholders on the MDR.

This represents an additional challenge for the implementation of the IVDR as often the same resources within regulatory authorities are needed for the implementation of the two regulations.

Additionally, the continued travel restrictions caused by the Covid-19 pandemic delay the completion of onsite initial IVDR and MDR audits with the risk of an audit “congestion” in 2021.

As stated above, if the postponement of the Date of Application of the IVDR is required, it is critical this decision is taken by the end of 2020 and the focus on the IVDR implementation is maintained by all stakeholders to ensure all necessary tools and resources are available well ahead of the revised Date of Application.

About Team-NB

Team-NB, The European Association for Medical Devices of Notified Bodies is dedicated to ensure a high level of patients' safety and confidence. Our three main areas of focus, have been and will remain:

- The promotion of innovation, but innovation that is backed by solid safety and effectiveness data. The certification of manufacturers' products is essential to continue the confidence in Medical Devices and In-Vitro Diagnostic products.
- Our support to notified bodies, through our detailed and state of the art guidance documents, ensures a consistent standard is achieved by our members throughout Europe.
- Ultimately, Team-NB works to ensure continuous improvement of products, leading to increased patient access to safe innovative products.

Our main objectives, have been and will remain:

•To improve communications with the EC Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies

•To promote high technical and ethical standards in the functioning of Notified Bodies

•To increase competences in decision making processes

•To make available to the sector a competent work forces as quickly as possible

•To protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the three medical device directives.