The European Association
Medical Devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Boulevard Frère Orban, 35A
B – 4000 Liège BELGIQUE
Tel.: + 32 (0)4 254 55 88

E-mail: secretary@team-nb.org
Web: http://www.team-nb.org
Bank : IBAN BE09 3401 5174 8757
VAT : BE 0864.640.677

Editors : Francoise SCHLEMMER	Date : 15/12/2020

Position paper

Directives expiring certificates – impacts and suggested solutions

Thanks to EUSurvey, the European Commission's tool, at the end of August 2020, all Medical Devices Notified Bodies (n=54) were invited to participate in the survey "**MDR: Increasing Transparency of MDR Designation Process 08-2020**". The survey was closed on September 25th. At that time, 34 Notified Bodies responded to the survey.

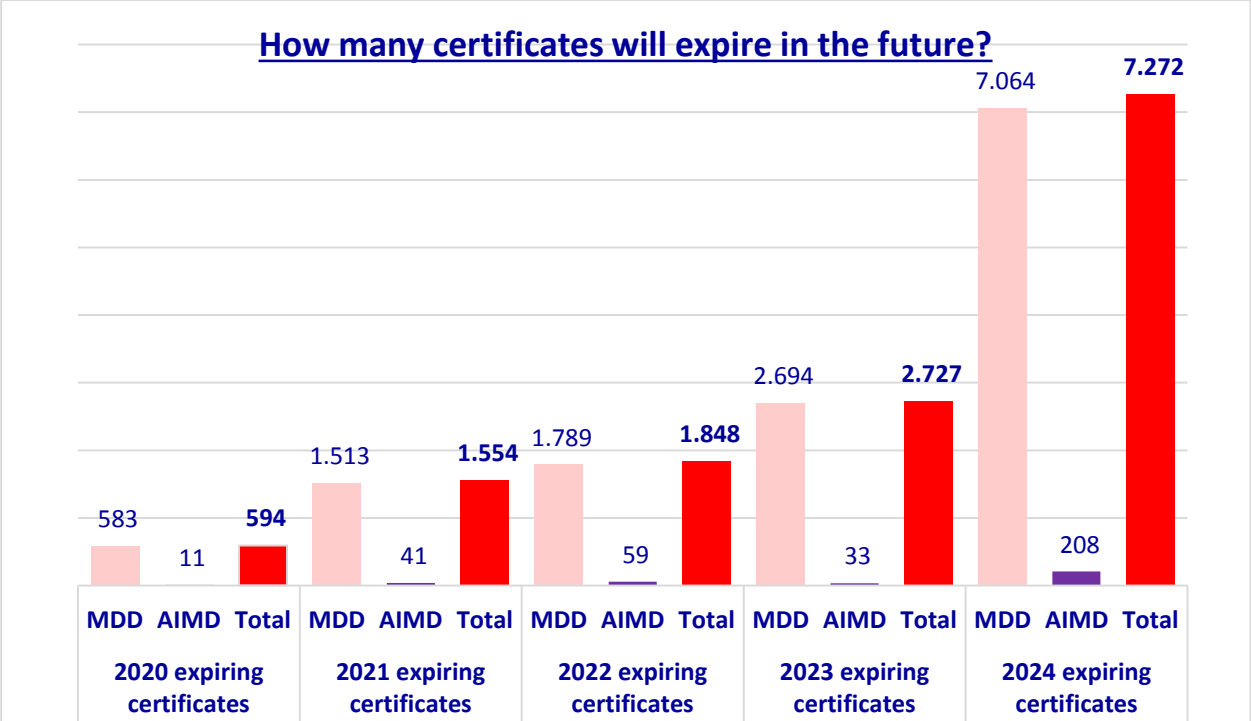
The objective of this survey was to provide transparency on Notified Bodies joint capacities to allow successful implementation of the MDR.

The main goal of this survey was to provide updated information about the designation process. Additionally, the survey addressed the number of certificates subject to transition from MDD/AIMDD to MDR during the 'soft transition period' between 2021 and 2024.

The **distribution of certificates' expiration** over the transition period of Directives certificates will be **challenging**.

The question regarding the certificates subject to transition from AIMDD/MDD to MDR was:

« How many certificates will expire in the future?
Expiring certificates include QM- and product-related certificates. »



From these results, it is clear that in 2024, the number of expiring certificates will induce a peak in the workload of notified bodies that will be difficult to manage. It is time to consider solutions that will allow this peak to be distributed in order to manage it. Moreover, for certificates expiring in 2021-and first half of 2022 (1554 in 2021 and as a rough estimation approximatively 50% of the expiring certificates in 2022: 924 certificates, altogether: 2478 certificates), taking into consideration the certification process duration, an immediate solution is necessary, otherwise devices will not be available for patients.

Two suggestions include:

- Acceptance of remote audits under the Regulations to allow progress to be made in the transition from Directives to Regulations now
- Encouragement of manufacturers to continue to make progress with Regulation submissions, so that not all submissions are made in 2024

Indeed, the amount of certificates under the Directives (MDD and AIMDD) expiring in 2024 will be increasing by more than 2,6 fold in comparison with the preceding year. These data do not show the increasing number of Regulation certificates that have greater needs for interim conformity assessment activities (e.g. PSUR, SSCP). These data also do not any other activities that the Notified Bodies must complete (e.g. re-assessment of Regulation designations) due in 2023 and 2024. Thus it is definitely a challenge to be taken into consideration if we want to avoid the risk of shortages of medical devices in 2024 which could lead to risks for patients.

In conclusion, the survey on MDR: Increasing Transparency of MDR Designation Process 08-2020" shows with the responses to the question on "How many certificates will expire in the future?" that solutions have to be found to flatten the high waves in the workload of notified bodies in 2023-2024 to avoid risks for the public health.

The full survey was presented during the October 2020 NB-Med meeting thanks to Hans-Heiner Junker who initiated the survey towards all designated notified bodies.

In case of any further clarification needed, please contact schlemmer@team-nb.org.