The European Association Medical Devices - Notified Bodies

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PRESS RELEASE

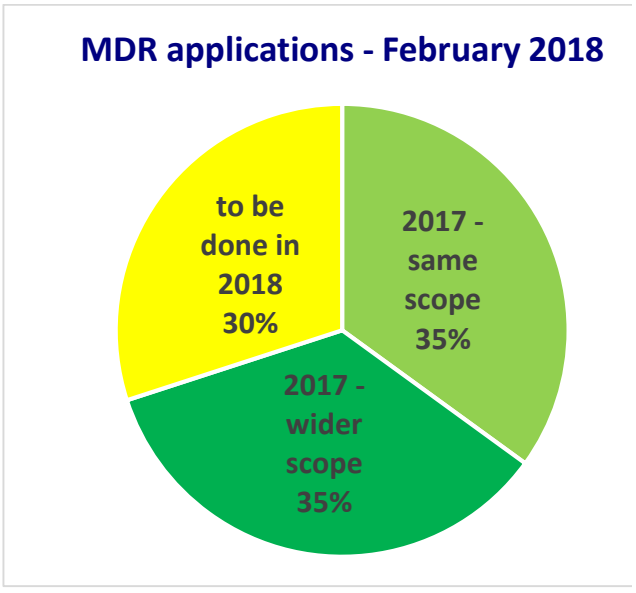
On-going surveys on NBs applications against new regulations

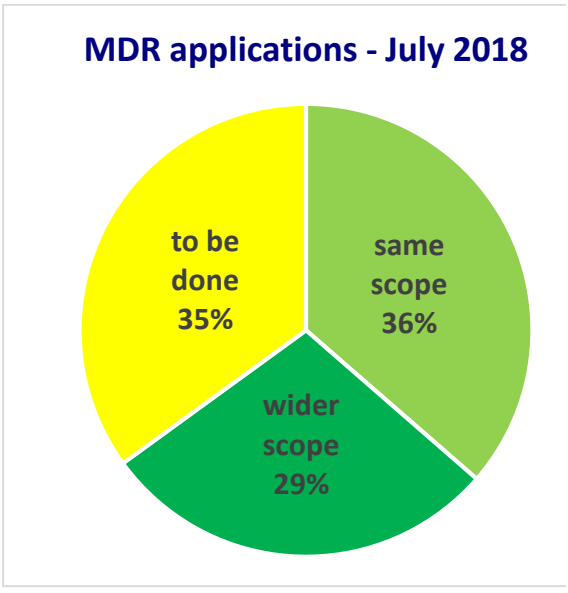
Following interest from the sector concerning the designation process in the framework of the MDR / IVDR regulations and as an act of transparency, you will find below data concerning the applications by the Team-NB member notified bodies under the MDR and how this compares with their current scope under the two current directives AIMDD/MDD.

This data collection was completed on the 17th July thanks to a survey tool in CIRCABC. The data relates to seventeen members who responded to the survey.

You will find below some commented graphs with comparison to the February survey completed earlier this year.

As far as the **applications submitted** are concerned as well as the width of the scope, the two surveys are comparable.





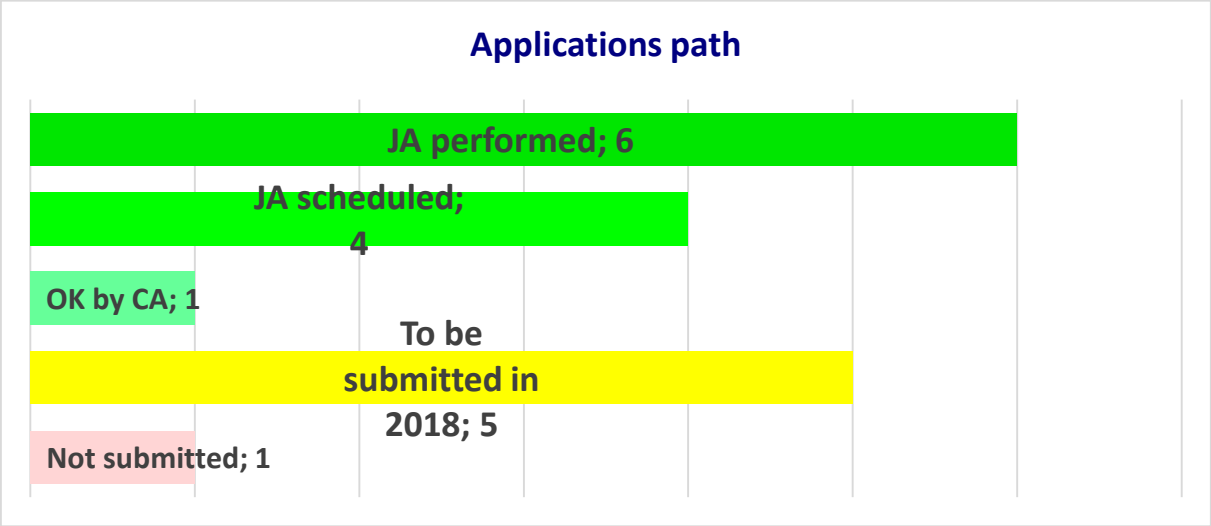
In the framework of the EU Medical Devices Regulation 2017/745 on the basis of the 17 answers which are representing 74% of the members, we can extrapolate that

- ✓ 65% of the Team-NB members submitted their application to be designated against the MDR before July 17th, and
- ✓ 44% of them applied for a wider scope, the other 57% for the same scope and none of them for a smaller scope.

In order to detail the **designation process progress,** the July survey asked the participants the status of their application. You will discover in the graph below the details.

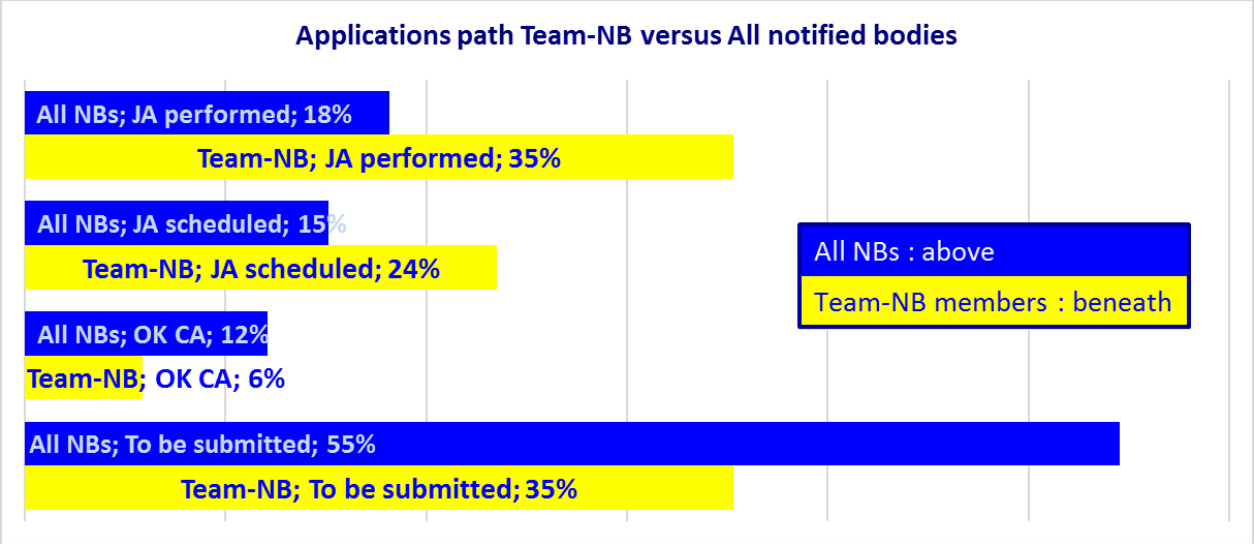
The analyse shows that within the ones which submitted their applications

- ✓ 54% of the Team-NB members which submitted their application have already had the Joint audit, and are now in the process of addressing the observations,
- ✓ 36% of those have their joint audit scheduled in 2018 and
- ✓ 10% is to be planned.



The July survey included Team-NB and non-Team-NB members notified bodies. There has been a total of 33 participants; 17 of which were Team-NB members.
In comparing those 2 entities, you can discover that

- ✓ 65% of the Team-NB members entered the designation process although
- ✓ 45% of the non-members group entered the designation process.



Moreover, in the answers to the question “What product groups are covered by your application?”. We can see that **all the codes are covered** by at least 5 notified bodies members and in most of the cases by more than 10 notified bodies.

In this framework, in more specific areas, we discover that

- ✓ 71% of the Team-NB members intends to provide CE marking following article 16 (“Cases in which obligations of manufacturers apply to importers, distributors or other persons”) and
- ✓ 44% of them intends to provide CE marking following article 17 (“Single-use devices and their reprocessing »)
- ✓ 65% of them intends to obtain a designation to be allowed to certify against Annex XVI (“Products without an intended medical purpose») and
- ✓ 76% plans to accept applications for “reusable surgical instruments”

As you can see, the results of this survey confirm the intent of the Team-NB members to do their best to allow the designation process to be as quick as possible.

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