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The European Association
Medical Devices - Notified Bodies

Notified Body Position Paper

Notified Body position paper on MDR/IVDR Implementation

The purpose of this position paper is to address concerns of MDR/IVDR designated Notified Bodies in relation to MDR/IVDR Implementation respectively from 26th May 2021 or 26 May 2022 to 26th May 2024.

1. EXECUTIVE SUMMARY

Team NB appreciates the Commission's efforts to implement the new Medical Devices Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746).

These two new EU Regulations aim to improve patient safety by strengthening requirements for Manufacturers and Notified Bodies.

2. BACKGROUND

With an increased demand for medical devices and given that AIMDD/MDD/IVD certificates will cease to exist in 2022, 2023 and 2024, there is a concern from Notified Bodies that there will be a potential risk of shortage of medical devices/IVDs for patients in Europe.

Team NB would like to present concerns and propose solutions in order to ensure availability of medical devices for the European population.

3. CONCERNS

3.1. NBs capacities in 2022/2023/2024 given the amount of expiring AIMDD/MDD/IVDD certificates

There is certain amount of Notified Bodies in the process of MDR/IVDR designation, however given the designation duration timelines it will be difficult to have appropriate number of NBs (51 for MDD and 21 for IVDD)

As regards IVDR, there is lower amount of IVDR designated Notified Bodies and longer certification process comparing to IVDD certification process.

NBs resources are already facing challenging situation as, in addition to the issues related to the pandemic, they are performing the Directives surveillance activities and, in parallel, managing new MDR/IVDR application activities. This challenging situation will continue in 2022/2023 and in 2024 as the Directives certificates reach their expiry date. According to the latest polls performed by Team-NB and the European Commission, the majority of the valid Directives certificates are expiring in the first five months of 2024.

Specifically for MDR, it should be noted that the postponement of the MDR date of application resulted in the extension of a high number of MDD certificates and delay in the submissions of MDR applications from manufacturers. Furthermore, only 24 NBs are currently designated for MDR and only 6 for IVDR versus 51 for the MDD and 21 for the AIMDD /IVDD.

MDR Transition period was compressed by 1 year and initiation of MDR Audits is delayed due to travel restrictions, hence MDR certification process resulted in a very low amount of MDR certificates as of now (502 MDR certificates and 31 IVDR certificates as of September 2021 European Commission Survey on certifications and applications). Travel restrictions also impacted the execution of audits and the IVDR certification process.

These circumstances are inevitably leading to an extreme bottleneck in the processing of MDR/IVDR certification by NBs, which will increase towards 2024 proportionally to the amount to expiring Directives certificates and will most probably prevent high number of devices currently certified under Directives from timely transition by 26 May 2024.

Reference https://www.team-nb.org/wp-content/uploads/2020/12/Team-NB-PositionPaper-ExpiringCertificates-20201215.pdf

Proposed solutions:

- Options should be examined for allowing toleration of manufacturers whose Directives certificates expired prior to successful completion of MDR/IVDR certification for as long as there is evidence of an MDR/IVDR application successfully accepted by a notified body
- A further extension of the IVDR transition period beyond 26 May 2024 should be examined (e.g. until 26 May 2025) considering very limited grace period
- Manufacturers should be stimulated to apply for MDR/IVDR certification as soon as possible, even if their Directives certification is not yet close to expiry
- MDR/IVDR designation process timeline should be shorter to increase the number of available NBs as quickly as possible

3.2. MDR/IVDR remote audits are not harmonised between member states

Only 5% of MDR/IVDR Audits are done remotely following Commission Notice 2021/C 8/01
implementation. Generally, no MDR/IVDR initial audits performed remotely, with the exception of some “clinically necessary” devices performed. A harmonised governance by member states/competent authorities is needed for MDR/IVDR remote audits. NBs are expecting to have practical ways to perform remote MDR/IVDR initial audits and MDR/IVDR surveillance audits if the pandemic should continue or reoccur in the next years.

Competent authorities should agree on the MDR/IVDR audits best practice and allow NBs to perform MDR remote audits given that the MDR date of application has already passed and only a small amount of MDR certificates could be issued (approximately 500 MDR certificates in Europe).

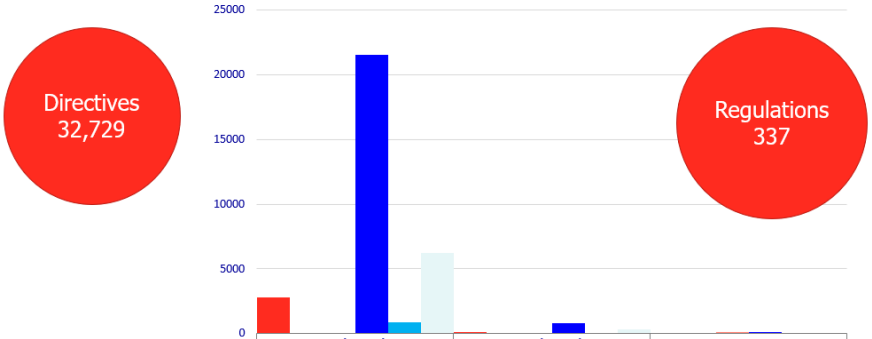
The same should applies for IVDR remote audits as the IVDR date of application is approaching and the percentage of devices that will benefit from the grace period is estimated to be less than 10%.

The MDR/IVDR transition timeline will be unachievable if NBs cannot perform MDR/IVDR Initial Remote Audits and MDR/IVDR Surveillance Audits.

The Commission Notice 2021/C 8/01 allows MDR/IVDR remote audits if there is a risk of shortage for medical devices, however it is not clear for NBs how to justify and verify the "risk of shortage". NBs need clear criteria for the interpretation of "risk of shortage". NBs need harmonised instructions from European Commission and Member States on how to define and verify "risk of shortage".

It was possible to perform approximately only 5% of initial Regulation audits partially remote as 143 initial Regulation Audit days are performed while at the same time 2769.2 Directive Audit days are performed.

❖ Number of Remote Audit Days by Type



	AIMDD/MDD/IVDD - Legal Manufacturers	AIMDD/MDD/IVDD - Suppliers / Subcontractors	MDR/IVDR - Legal Manufacturers
Initial	2769,2	98	
Initial - 'clinically necessary'			35
Initial - 'partially remote'			108
Surveillance	21511,1	818,1	112
Extension to Scope	896	50	22
Re-assessment	6244,7	343	60

Reference: https://www.team-nb.org/wp-content/uploads/2021/06/CIRCABC-Remote-Audit-Analysis-May-2021.pdf

Proposed solutions:

- Authorized Initial and Surveillance MDR & IVDR remote audits with documented justified risk based approach and not only under "risk of shortage conditions" as per Commission Notice 2021/C 8/01
- Alignment between Competent Authorities to authorise remote audits

3.3. Impact of Covid-19 on PMCF/PMPF for legacy devices

The impact of Covid-19 pandemic has been detrimental to healthcare research and development, with reports of over 80% of clinical investigations disrupted or halted.

Proposed solutions

- Acceptance of other types of clinical/performance data that may be collected to support an MDR/IVDR application when previously agreed PMCF/PMPF data collection has been impacted by Covid-19.
- Acceptable criteria of alternative data e.g. remote survey considerations, remote assessment data
- Acceptance criteria for the notified body to consider when assessing clinical data impacted by Covid-19
- Acceptance Criteria for when notified bodies can allow for PMCF activities conducted under the AIMDD/MDD (that have not completed due to the pandemic) that can continue under MDR
- Considerations for notified bodies when evaluating clinical/performance data that has been impacted by Covid -19 pandemic e.g. availability of medical alternatives, PMCF/PMPF follow up intervals, reducing MDR/IVDR certificate validity to coincide with data collection.

3.4. Harmonisation elements missing

As to this date, there are several important MDCG guidance's missing **,** as example MDCG Guidance on appropriate surveillance according to Article 120(3) and MDCG guidance Updates of guidance documents and templates on the designation and re-assessment process and MDCG Guidance - Updates of guidance documents and templates on qualification and authorisation of personnel .
We can notice lack of MDCG Guidance's, Common specifications, Harmonised standards and Implementing acts under Regulations

Proposed solution
NBs should be entitled to establish "good practices" for a harmonised approach. These documents could be prepared endorsed at the Team-NB level as the 1st step. In a 2nd step, the paper could be updated/endorsed by NBTG and then NBCG-Med.

4. IN CONCLUSION

Notified bodies believe that risk of interrupted supply of medical devices could be mitigated if proposed solutions are considered and implemented. If additional measures would be needed for MDR, notified bodies consider the concept of 'progressive roll-out', as included in COM proposal for amending the transitional provisions for IVDR[1], as more useful than another postponement of the MDR.

[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices; 2021/0323 (COD)