Entering Year #3 of the IVDR and MDR:
…the finish line in sight?

Swedish MedTech Regulatory Summit
21 May 2019

Oliver Bisazza, Director Regulations & Industrial Policy
MedTech Europe

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Reminder: Our Advice Last Year* to Swedish Industry

1. RUN!

- **Timelines are tight!** May 2020/2022 is yesterday
- **Do what you can**, when you can, e.g., start with quality systems, labelling, economic operators, etc.

2. ADAPT!

- **Engage Notified Bodies!** You may need to contact several, and they may not all be available
- **Remember Delegated/Implementing Acts and guidance**. They'll come at different points in time

3. SMILE!

- **Your trade associations are here to help!** ☺

ALL STILL VALID!
BUT THE STAKES ARE HIGHER…

**MedTech Europe presentation at the 21 March 2018 Regulatory Summit*

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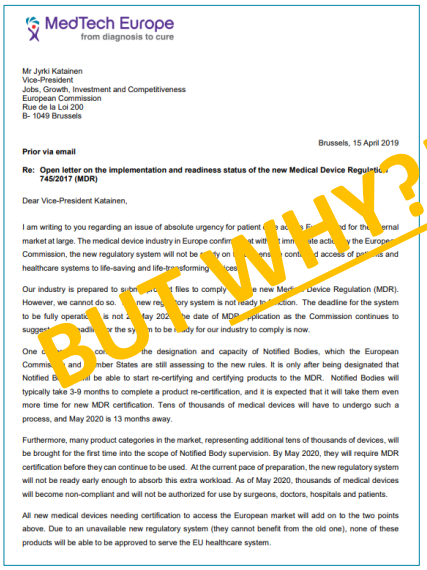
IVDR/MDR Implementation Status: *Critical*

- On 15 April, MedTech Europe wrote to European Commission Vice-President Katainen, calling on the Commission **to take immediate and decisive action** to address an "*issue of absolute urgency for patient care across Europe*."
- Our underlying concern is that **the new EU medtech regulatory system is not on-track to be "*ready on time to ensure continued access of patients* and healthcare systems to life-saving and life-transforming devices."**



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Mr Jyrki Katainen
Vice-President
Jobs, Growth, Investment and Competitiveness
European Commission
Rue de la Loi 200
B- 1049 Brussels

Brussels, 15 April 2019

Prior via email

Re: Open letter on the implementation and readiness status of the new Medical Device Regulation 745/2017 (MDR)

Dear Vice-President Katainen,

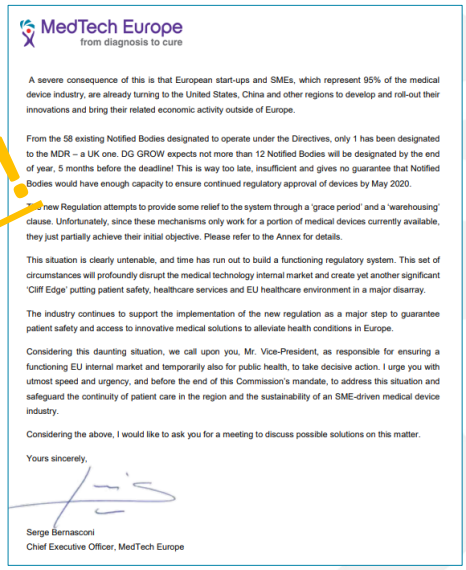
I am writing to you regarding an issue of absolute urgency for patient c… and for the internal market at large. The medical device industry in Europe confir… with t… immediate actio… by the Europe… Commission, the new regulatory system will not be ready on t… ensure continued access of p… and healthcare systems to life-saving and life-transforming devices.

Our industry is prepared to submit our files to comply with the new Medical Device Regulation (MDR). However, we cannot do so. The new regulatory system is not ready for action. The deadline for the system to be fully operational is not 26 May 2020, the date of MDR application as the Commission continues to suggest. A deadline for the system to be ready for our industry to comply is now.

One of the tools for the designation and capacity of Notified Bodies, which the European Commission and Member States are still assessing to the new rules. It is only after being designated that Notified Bodies will be able to start re-certifying and certifying products to the MDR. Notified Bodies will typically take 3-9 months to complete a product re-certification, and it is expected that it will take them even more time for new MDR certification. Tens of thousands of medical devices will have to undergo such a process, and May 2020 is 13 months away.

Furthermore, many product categories in the market, representing additional tens of thousands of devices, will be brought for the first time into the scope of Notified Body supervision. By May 2020, they will require MDR certification before they can continue to be used. At the current pace of preparation, the new regulatory system will not be ready early enough to absorb this extra workload. As of May 2020, thousands of medical devices will become non-compliant and will not be authorized for use by surgeons, doctors, hospitals and patients.

All new medical devices needing certification to access the European market will add on to the two points above. Due to an unavailable new regulatory system (they cannot benefit from the old one), none of these products will be able to be approved to serve the EU healthcare system.



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A severe consequence of this is that European start-ups and SMEs, which represent 95% of the medical device industry, are already turning to the United States, China and other regions to develop and roll-out their innovations and bring their related economic activity outside of Europe.

From the 58 existing Notified Bodies designated to operate under the Directives, only 1 has been designated to the MDR – a UK one. DG GROW expects not more than 12 Notified Bodies will be designated by the end of year, 5 months before the deadline! This is way too late, insufficient and gives no guarantee that Notified Bodies would have enough capacity to ensure continued regulatory approval of devices by May 2020.

The new Regulation attempts to provide some relief to the system through a 'grace period' and a 'warehousing' clause. Unfortunately, since these mechanisms only work for a portion of medical devices currently available, they just partially achieve their initial objective. Please refer to the Annex for details.

This situation is clearly untenable, and time has run out to build a functioning regulatory system. This set of circumstances will profoundly disrupt the medical technology internal market and create yet another significant 'Cliff Edge' putting patient safety, healthcare services and EU healthcare environment in a major disarray.

The industry continues to support the implementation of the new regulation as a major step to guarantee patient safety and access to innovative medical solutions to alleviate health conditions in Europe.

Considering this daunting situation, we call upon you, Mr. Vice-President, as responsible for ensuring a functioning EU internal market and temporarily also for public health, to take decisive action. I urge you with utmost speed and urgency, and before the end of this Commission's mandate, to address this situation and safeguard the continuity of patient care in the region and the sustainability of an SME-driven medical device industry.

Considering the above, I would like to ask you for a meeting to discuss possible solutions on this matter.

Yours sincerely,

Serge Bernasconi
Chief Executive Officer, MedTech Europe

BUT WHY?!

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Because THIS has barely changed in the past 18 months!

Where we stand with the main 'building blocks' of the new regulatory system

Implementing Acts:	**2 are published…**but at *least 16 more* are needed
Guidance documents:	**A few are done…**but most are *still to-do*
Expert panels:	**None yet…**
EU reference laboratories:	**None yet…**
Common specifications:	**None yet…**
Notified Bodies:	**1 is notified**…in the ***United Kingdom***

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Time is RUNNING OUT!

MDR

26 May 2020

= 12 calendar months from now

But really, we're out of time!

IVDR

26 May 2022

…and the IVD Regulation deadline is much closer than it seems!

Industry wants to comply, and will!

We have always **supported** the new system

But regulators must **enable** us to get products approved

We **cannot** submit files for review without **critical infrastructure**

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But really, we're out of time!

IVDR

26 May 2022

…and the IVD Regulation deadline is much closer than it seems!

What is at stake

Patient care

Product supply to hospitals

Innovation

Small and medium-sized enterprises

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Our Call to Action for European Authorities

Implement the new regulatory system **faster** and with more **efficiency**:

1. **Notified Bodies**: Designate them faster!
2. **Re-certification**: Ensure the procedure works for all products
3. **Eudamed**: Deploy the new database with workable IT specifications and implementation timelines
4. **(Quality) Guidance**: Publish it in the most urgent areas
5. **Scientific Bodies**: Rapidly establish the new expert panels and EU reference laboratories
6. **Delegated and Implementing Acts**: Publish the most-needed ones, including certain 'system-critical' common specifications
7. **Harmonised Standards**: Ensure they are available in the highest-priority areas first

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1 Notified Bodies

Designate them faster!

Problem

- Virtually no Notified Bodies (NBs) are available yet, and 26 May 2020 is 12 months away!
- Too few NBs are in the pipeline, and more are badly needed, especially for the IVD sector
- For those few NBs that are in the pipeline, designation is going too slow…and industry is already experiencing certification bottlenecks and delays under the former Directives!

Our call to authorities

- Acknowledge that we are not on-track, and prepare for future insufficient NB availability
- Develop and communicate a coordinated, EU-wide solution that ensures that manufacturers can continue CE marking, even if they temporarily become 'orphans'
- Accelerate designation by removing as much bureaucracy from the process as possible

Deadline

- **MDR**: European solutions are needed ASAP to avoid potential market disruption!
- **IVDR**: Designations need to start in earnest from mid-2019 onwards

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Re-certification

Ensure the procedure works for all products

Problem

- Specific families of existing products are at special risk of becoming unavailable, e.g.,
  - Products ineligible for the 'grace period' that extends until May 2024
  - Products eligible for the grace period but unable to use it due to insufficient NB capacity

Our call to authorities

- Put in place a staged (re-)certification sequence for NBs to follow, e.g., giving priority to product families whose supply to the healthcare system are at exceptional risk
- Agree workable re-certification timelines and processes for existing 'combination products,' i.e., medical devices that incorporate ancillary medicinal substances

Deadline

- A clear, actionable plan must be in place by August 2019

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The new Eudamed Database

Deploy it with workable IT specs and implementation timelines

Problem

- Without a fully functional database, the Regulations' benefits would be severely reduced
- Some parts of the database are encountering delays, e.g., due to debates about whether existing devices should be (re-)registered in Eudamed…and other parts are being rushed!
- Manufacturers need sufficient time to adapt their IT systems to Eudamed's technical specs

Our call to authorities

- Rapidly define and validate all Eudamed modules needed by May 2020 to apply the MDR
- If this cannot be achieved with clear, dependable timelines, publish contingency guidance so that stakeholders know how to proceed while Eudamed is still being built
- Only make the modules compulsory 18 months or more after publishing stable IT specs
- Prioritise! Focus on delivering a fully functional database for IVDR/MDR-certified products

Deadline

- **Actor** registration module: Deploy it 'immediately' so we can start getting SRNs!
- **UDI, device** and **certificate** registration modules: 2nd priority. Deploy them ASAP
- **Vigilance** and **clinical** modules: Ensure 18 months minimum before 'go live' date

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(Quality) Guidance

Publish it in the most urgent areas

Problem

- Many (most…) needed guidance documents are still to be published
- Some are as important as the 'core infrastructure' supporting IVDR/MDR implementation

Our call to authorities

- MDR: Publish ASAP guidance on software classification, Eudamed and UDI, transitional provisions, post-market surveillance (PMS), and on Article 61.6 ('sufficient clinical data')
- IVDR: Progress urgently with guidance on IVD classification, performance evaluation, conformity assessment, PMS, companion diagnostics and software-specific aspects

Deadline

- **MDR**: ASAP and ideally by August 2019
- **IVDR**: Everything must be published by May 2020 latest
  - Guidance on IVD classification is needed sooner, by Q3 2019

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The new Scientific Bodies

Rapidly establish the expert panels and EU reference labs

Problem

- These bodies must be set up for the very first time, and thus constitute 'new territory'
- They are required for IVDR/MDR certification of innovative, highest-risk devices

Our call to authorities

- Establish these bodies as soon as possible, and while the needed Implementing Acts are being adopted, e.g., Implementing Acts specifying the bodies' roles and fees
- Ensure that these bodies function as efficiently as possible, with clear, strict scopes
- For expert panels specifically: Clarify if certain branches of medicines will take priority over others, or whether all therapeutic/diagnostic areas are of equal priority

Deadline

- **MDR**: Expert panels for all therapeutic areas must be up and running by end 2019
- **IVDR**: May 2020 is the latest acceptable deadline by which the fully functional EU reference laboratories, expert panels and common specifications are needed

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Delegated and Implementing Acts

Publish the most-needed ones, including certain 'system critical' common specifications

Problem

- Even the most 'mandatory' Acts are only starting to be published into Year #3 of transition
- Implementing Acts laying down common specifications (CS) are crucial for the conformity of some devices, e.g., Class D IVDs, and 'aesthetic' medical devices listed in MDR Annex XVI
- Manufacturers ideally need many months to adapt to the changes these Acts will bring

Our call to authorities

- Publish clear, ambitious target deadlines for developing and publishing all foreseen Acts
- Consider 'upgrading' the priority of certain Acts that are not currently in the Rolling Plan, e.g., the Act on free sale certificates, or the Act on implant card exemptions
- Expedite as much as possible the most-needed CS, e.g. ex-IVDD CTS → IVDR CS

Deadline

- **Horizontal Acts** – e.g., those needed to specify the roles and fees for expert panels – are needed ASAP and by no later than August 2019
- **IVDR**: CS need to be developed and published by end 2019 (and no later than May 2020
- **MDR**: CS on Annex XVI products are needed ASAP and by no later than August 2019

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Harmonised Standards

Ensure they are available in the highest-priority areas first

Problem

- Harmonised standards are invaluable to ensure products are safe and work as intended
- They contribute to consistent conformity assessments & have been key compliance tools
- However, they are currently on-track to be absent from the IVDR/MDR until (potentially several) years from now…this leads to uncertainty about how to proceed.

Our call to authorities

- Prioritise the harmonization of standards in areas of most critical horizontal importance, e.g., in areas like symbols, labelling, risk management, and good clinical (study) practice.
- Ensure all stakeholders including CEN/CENELEC work together, because time is running.

Deadline

- May 2020 as ideal (but no later than May 2021)

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In Summary

1. **Notified Bodies**: Designate them faster!
2. **Re-certification**: Ensure the procedure works for all products
3. **Eudamed**: Deploy the new database with workable IT specifications and implementation timelines
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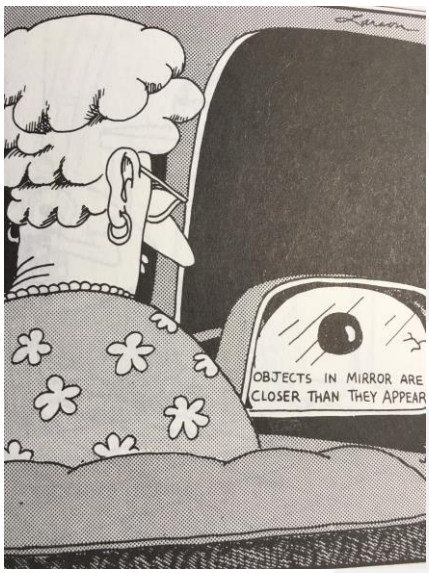
Take-home Messages

To Industry

- **Stay vigilant!** These final months are going to be very tight, and much could still change
- **Speak up!** If you experience challenges, engage your Ministry of Health & competent authority to ensure your voice is heard!

To Authorities

- **Please HURRY UP!** It will soon be too late to deliver the regulatory system's most critical infrastructure, and patient care is at stake!
- **Communicate!** Industry needs to know **now** what steps you will take if the IVDR/MDR aren't successfully implemented on-time!



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Thank you
for your time
For more info, please contact:
Oliver Bisazza
O.Bisazza@medtecheurope.org
www.medtecheurope.org

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