Stockholm, 22 oktober 2024

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Angående akut behov att säkra tillgången till medicinteknik

Som företrädare för de medicintekniska och laboratorietekniska företagen i Sverige vänder vi oss till er inför det kommande EPSCO-mötet i december. Vi har tidigare fört en dialog med er kring utmaningarna med implementeringen av IVDR och MDR och vet att ni är väl insatta i de utmaningar som de medicin- och laboratorietekniska företagen ställs inför på grund av detta och hur problemen direkt påverkar den svenska hälso- och sjukvården.

Tillsammans med våra branschkollegor i Europa vädjar vi från svenskt håll, genom de svenska branschorganisationerna Swedish Medtech och Swedish Labtech, till flera av medlemsstaternas ministrar med ansvar för hälso- och sjukvård. Vi vill att ni lyfter en rad allvarsamma faktorer som vi ser orsakar både att produkter försvinner från den europeiska marknaden och att ny innovativ teknik inte når ut. Detta påverkar patientsäkerheten och folkhälsan i hela Europa.

Vi vill understryka att branschen till fullo stödjer målen för såväl MDR som IVDR och gör sitt yttersta för att efterleva regelverken. Dock står vi idag inför en kritisk situation där dessa två regelverk inte harmoniserar med de mål som ursprungligen avsågs av EU-lagstiftaren. Oförutsägbarheten och komplexiteten hos regelverken leder till att många medicin- och laboratorietekniska produkter som idag finns på marknaden försvinner, men även att ny innovativ teknik inte når svenska och europeiska patienter. Vi riskerar därtill konkurrenskraften för hela den breda medicin- och laboratorietekniska branschen och överlevnaden för våra små och medelstora företag. Denna utveckling måste stoppas innan den ytterligare påverkar den europeiska hälso- och sjukvården.

Swedish Medtech och Swedish Labtech föreslår tillsammans med våra europeiska systerorganisationer tre områden att agera inom. Ni kan läsa mer utförligt om dessa i bilagt dokument.

A. Vi vill se att EU-kommissionen utvecklar ett paket av lagstiftningsreformer, en för IVDR och en för MDR, för att säkerställa att dessa förordningar uppfyller sina ursprungliga mål. Det är avgörande att de förbättrade regelverken uppfyller tre kriterier: att vara effektiva, innovationsvänliga och välfungerande.

B. Vi vill att EU-kommissionen -så snabbt som möjligt vidtar ett antal åtgärder enligt nedan för att stötta tillgången till medicin- och laboratorieteknik och säkerställa att den medicin- och laboratorietekniska

industrin överlever. Dessa åtgärder kan inte vänta till utvärderingen av regelverken är klar och fullständiga lagstiftningsreformer publicerats på EU-nivå

1. **Tid och kostnad för att certifiera produkter måste reduceras avsevärt**. Ett omedelbart agerande är nödvändigt för att stoppa den pågående negativa utveckling där produkter försvinner från marknaden och innovationer inte når Europa.

2. **Bedömning av förändring av en medicin- och laboratorieteknisk produkt måste göras mer effektivt** för att säkerställa att den senaste tekniken når patienterna snabbare.

3. **Ett snabbspår för innovation bör inrättas** för att möjliggöra att ny innovativ teknik kommer till Europa först eller parallellt med andra länder.

4. **Anpassa certifieringen så att den följer produktens livscykel.** Detta skulle ta bort en negativ faktor som riskerar att tillverkare skjuter certifieringen på framtiden. Det minskar också tröskeln för att tillverkare ska besluta att behålla produkter på den europeiska marknaden. Dagens krav ser vi skapar flaskhalsar under övergångsperioderna till reglerna.

C. EU-kommissionen måste fortsätta att vidta specifika åtgärder för att förbättra genomförandet av regelverken. Exempel på nödvändiga åtgärder är att reducera omfattningen av den tekniska dokumentationen, godkänna elektroniska bruksanvisningar i större omfattning än vad som görs idag samt låta EU gå med i Medical Devices Single Audit Program.

Det är viktigt att Sverige och Europa står väl rustat inför de globala hot och utmaningar som vi står inför, med antibiotikaresistens, framtida pandemier och klimatrelaterade hälsoeffekter. Det är därför nödvändigt att investera i en regelverksmiljö som prioriterar snabbhet, koherens och förenkling.

Vår önskan är att ni vid kommande EPSCO-möte ber EU-kommissionen leverera konkreta lösningar på de punkter vi har beskrivit i det här brevet. Visionen för den medicin- och laboratorietekniska branschen är att vi får regelverk för medicin- och laboratorieteknik som når upp till de mål som lagstiftaren menade skulle uppfyllas utan att på något sätt kompromissa med patient- och produktsäkerhet, prestanda eller kvalitet. Genom samarbete kan vi uppnå detta – till förmån för svenska och europeiska patienter inklusive hälso- och sjukvårdsystem.

Med vänliga hälsningar

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Annex

Three Key Areas of Action which are needed to bring critical improvements to the Medical Technology Regulations (Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations (EU) 2017/745 and 2017/746)

A. Legislative package of reforms

As an immediate outcome of the targeted evaluation running until end-2025 – **a package of legislative reforms each for the IVD Regulation and MD Regulation should be developed** to ensure that these regulations deliver on their original objectives and deliver critical and much-needed improvements across the system.

European Commission President Ursula von der Leyen has made "less red tape and reporting, more trust, better enforcement, faster permitting" a priority of her 2nd mandate (2024-2029)[1].

In line with this, it is important that each package of legal reforms for the IVD Regulation and MD Regulation explicitly incorporates principles which will **dramatically enhance efficiency** and **robustly increase Europe's attractiveness for innovation** in medical technologies by:

- Adopting processes which work end-to-end equally for the devices of today and the future – and including for larger unmet needs as for orphan and niche devices,
- Ensuring the system is predictable, 'lean' and able to adapt to changes,
- Realising a net reduction in cost, complexity and administrative burden,
- Incorporating a least-burdensome principle for both pre- and post-market regulatory processes while maintaining a high standard of safety & performance.

To underpin the above, **a single, dedicated governance structure** should be established which oversees and manages the regulatory system, with accountability for ensuring that safe and performing medical technologies can reach patients and health systems in a timely manner. Amongst other tasks, this governance structure also should ensure regulatory coherence with other EU legislation.[2]

B. Measures which need to be advanced as a matter of urgency

As urgently as possible – **several 'bridging measures' are needed to support devices availability and the viability of the medical technology industry**. These measures cannot wait until the targeted evaluation is concluded and full packages of legislative reforms are written and published into EU law. The process to realise full legislative packages could take years – time which patients and health systems do not have.

It is critical that devices developed and provided by the wider industry especially Small and Medium Enterprises (SMEs) stay available to patients. Both devices and SMEs are at risk of disappearing due to the current burden of the IVD Regulation and MD Regulation. Innovative medical technologies are not arriving in Europe as they should. These trends must be addressed immediately and before European

[1] Political guidelines for the next European Commission, 2024-2029.
[2] Numerous new requirements arrive for medical technologies every year, some with significant overlaps or misalignments with IVD Regulation and MD Regulation, or which necessitate device re-designs, updates to labelling or have other impacts.

healthcare is further impacted. **Several measures are needed as urgently as possible and should have sufficient legal weight to achieve the following:**

1. **Initial conformity assessment timelines and costs must be significantly reduced and made predictable.** Immediate action here is vital both for helping to halt the ongoing disappearance of today's devices and for attracting investment in bringing innovations to Europe. Manufacturers cite long and unpredictable timelines and costs as principle reasons for not transitioning devices to the IVD Regulation and MD Regulation[3] and for why 1 in 3 manufacturers are launching new innovations only or first outside of Europe[4]. Conformity assessment bodies ('Notified Bodies') consistently should offer dialogues pre-submission and during conformity assessment with the manufacturer to set out timelines and level of evidence expectations, with the outcome described in a formal binding statement. Conformity assessment timelines should be reduced to 6 months for Quality Management System and 3 months for Technical Documentation certification. Notified Bodies should publish ex-post reports on costs and timelines per device type to enable transparency on how much conformity assessment fees cost in total.

2. **Assessments of changes to medical technologies must be made more efficient to allow the latest technologies to reach patients swiftly.** The assessment of changes to medical technologies by Notified Bodies which are CE-marked under the European regulations, needs to be more efficient to ensure patients receive the latest technologies quickly. This is crucial for addressing the current workload of Notified Bodies and reducing the lengthy, unpredictable timelines for updating medical devices. Currently, even urgent device changes are seeing delays, with assessments often taking several months, though they should ideally be completed within one month. Patients can only benefit from these updates after the Notified Body has completed its review. To expedite this process, assessments should be limited to only necessary cases and handled promptly. The number of individual change notifications also should be minimized and streamlined through mechanisms like predetermined change controls.

3. **An accelerated pathway for breakthrough innovation should be put in place**.
   A clear regulatory pathway with an accelerated timeline of 120 days is needed to allow rapid uptake of breakthrough technologies. Today there is uncertainty over what is the appropriate level of evidence and what is acceptable to be provided pre- and post-market for groundbreaking, breakthrough and disruptive technologies. A well-defined, holistic approach to support innovation within our system will attract medical technology innovations to come to Europe faster and address unmet or undertreated medical needs of patients that are waiting for diagnosis, treatment, and care.

4. **Adapt certification to follow a life-cycle approach**.
   There is an immediate need for aligning certification with the lifetime of medical technologies. Removing the limited validity of certificates would eliminate a major bureaucratic burden and disincentive for manufacturers to bring and maintain devices under the IVD Regulation and MD

[3] For example, see survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023

[4] For examples, see survey report by MedTech Europe '*Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022*', October 2022. See survey report by MedTech Europe 'Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation', April 2022

Regulation and at the same time, help prevent anticipated Notified Body assessment bottlenecks during the transition periods to the regulations. Today, recertification for medical technologies is required every 5 years, which represents a high bureaucratic effort and re-investment burden without resulting in additional safety benefits. This is because the Notified Body already is required to continually assess devices and quality systems after their certification on an annual and ongoing basis. On that basis, Notified Bodies have today at their disposal sufficient mechanisms to allow for suspension of certificates where there is justification for doing so.

C. Specific measures to be pursued within the regulatory framework

On an ongoing basis – **specific measures to improve the implementation of the regulations should continue to be pursued through existing work streams and tools foreseen under the IVD Regulation and MD Regulation** (e.g. guidance, implementing acts, etc.).

While these should not be considered as a substitute for a package of legislative reforms – since the latter is needed to ensure a holistic approach is taken to addressing system deficiencies – there are many specific measures which can bring measurable improvements in the short-term.

The European medical technologies industry recognizes the considerable ongoing and important work of the European Commission and the Medical Devices Coordination Group[5] to improve the implementation of the IVD Regulation and MD Regulation across many work areas. Amidst these needed work streams, we highlight the following areas which are essential to support a smoother transition of devices to the regulations, reduce the burden of the regulations and help new innovations arrive in Europe, and ask that the European Commission and the Medical Devices Coordination Group:

- **Speed up and deliver on implementation of the 19 point action plan[6] to support the transition to the regulations**, in particular to
  - Realize more concrete measures to enable structured dialogues between manufacturers and Notified Bodies before and during conformity assessment,
  - Provide clear principles for leveraging evidence based on a 'no duplication of evidence review' principle,
  - Reduce the technical documentation sampling burden for both IVDs and MDs.
- **Work towards enabling electronic Instructions for Use (e-IFU) for <u>all</u> medical technologies**, following a risk-based assessment by the manufacturer.
- **Promote global convergence of regulations, in particular in the context of the International Medical Devices Regulators Forum (IMDRF) and their Medical Device Single Audit Program (MDSAP) initiative.** We call for the EU to join the MDSAP program as a Full Member and to enable recognition of MDSAP certificates for the purpose of CE marking medical devices and *in vitro* diagnostic medical devices.

[5] Including for example, to improve the framework for performance studies & clinical investigations, support pilot programs for orphan and niche devices, drive clarity on methodological frameworks for clinicals, put in place a framework for mandatory use of the European medical devices database and many other work streams.

[6] MDCG 2022-14 - Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs