Healthtech Finland

Proportionate and coherent regulation: enabling safe and efficient medical devices and IVDs for patients and citizens – when they are needed, where they are needed.

Contents

General remarks

HealthTech Finland thanks the Commission for opening the Call for Evidence for the medical device regulations (MDR and IVDR). The performance and safety of medical devices (MD) and in vitro diagnostics medical devices (IVD) is crucial to European patients. However, also the availability of devices to patients is a critical part of high-quality care and patient safety. The healthcare sector is also an important pillar of the EU economy, forming a significant part of EU exports.

Regulatory requirements, including third party conformity assessment, should be proportionate to risk and carefully balanced so that safe and efficient devices can be made available to those who need them, and unnecessary regulatory burden and high costs do not form a barrier to bringing devices to market, preventing essential devices reaching patients. It is in the interest of both industry and healthcare alike to set the balance right.

HealthTech Finland would like to emphasise, that although this call for evidence targets the MDR/IVDR particularly, EU legislation affecting medical device/IVD manufacturers should be considered as a whole. Currently, the medical device sector is struggling with the regulatory burden resulting from several different pieces of legislation: in addition to the MDR/IVDR, manufacturers may need to comply with or to prepare for compliance with the AI Act, Data Act, GDPR, GPSR, EHDS, Batteries regulation etc. The industry, and SMEs especially, face significant challenges including regulatory complexity, fragmentation, enforcement misalignment, outdated rules, compliance burden, and legal uncertainty across legislation. The current landscape requires SMEs to navigate multiple overlapping frameworks simultaneously, creating substantial administrative overhead.

This legal complexity encompasses conflicting regulations, regulatory gaps, data protection challenges, AI Act compliance requirements, medical device regulations, and administrative law requirements. The complexity is particularly acute for SMEs operating in digital healthcare technology sectors, where companies must navigate multiple frameworks including the European Health Data Space (EHDS), the EU AI Act with its high-risk AI system classifications, and medical device regulations such as the EU Medical Device Regulation (MDR). It should also be acknowledged that for the industry, the regulatory burden does not end at EU regulations, but export companies need to take into account the requirements of other jurisdictions, which despite international harmonisation efforts (e.g. through the International Medical Device Regulators Forum, IMDRF), are often not very well aligned with EU requirements.

It is important to note that the cost rises associated with the MDR/IVDR are not insignificant. For many IVD SMEs, the cost of notified body conformity assessment has in recent years become a significant barrier to market, not only for new products, but also for keeping old devices on the market. In general, the increase in cost of NB evaluations going from the previous MD and IVD directives to the current regulations is estimated to be considerably over 100%, as proved by several examples from HealthTech Finland member companies. For one member company, the estimated cost for third-party conformity assessment for a single product line (IVD) was approximately 1/10 of the annual turnover! Such cost increases are unsustainable without external funding. However, external equity funding is not readily

available for small companies to cover new regulatory costs for legacy products, without novelty value. It is feared that such costs will continue to form a barrier, especially to SMEs and start-up companies to introducing new, innovative products to the market. Moreover, previously marketed niche products may be withdrawn from the market due to regulatory costs being excessive and not commercially justified.

An additional unintended consequence of the IVDR is the possible long-term rise in the so-called in-house manufacturing of IVDs. As availability and costs of tests have become a problem, clinical laboratories are turning more to in-house production. In-house tests, although subject to the requirements of the General performance and safety requirements of annex I, as well as the additional conditions of article 5.5, do not undergo third-party conformity assessment. Thus, instead of better-quality CE-marked tests being offered and used in healthcare, actually more tests may now be produced in-house, with variable quality and less oversight. Although there will always be real specific needs for in-house manufacturing of tests, the intention of the IVDR was not to transfer test manufacturing to smaller scale, less-controlled environments in healthcare organisations. Changes to the IVDR are proposed that would better enable the industry to provide CE-marked tests also for small-volume applications, where the current cost structure under the IVDR is unworkable. This would allow laboratory professionals to direct resources more efficiently to testing, and serving patients, instead of having to take over also manufacturing of tests.

A similar phenomenon to the increase of in-house IVDs, but for possibly slightly different reasons, has been observed with medical software solutions: healthcare organisations are eager to build their own digital solutions, possibly with artificial intelligence involved, for various medical applications, instead of using CE-marked commercial solutions. In these cases, in addition to price, the fast development pace, not matched by conformity assessment timelines and complicated change control, may make in-house solutions seem more flexible and lucrative. Additionally, regulatory requirements may just not be familiar to actors, but surveillance of uncompliant medical device software in healthcare organisations is just not sufficient.

It is feared that instead of innovations being fostered inside the EU, established actors will continue to manufacture and sell increasingly outdated and inefficient products on the EU market while much of the innovation will come from outside the Union. Without changes to the regulations, innovations in the field of medical devices will come from regions where small companies have a lower threshold to introduce their new products to the market, grow, and enter the EU market after they have reached the financial position necessary to do so.

To solve this challenge, it is important that the MDR and IVDR are developed further, to incorporate more proportionality into the system, so oversight is better matched with device risks, taking into account recent advances in healthcare, such as digitalisation and AI. It is also important that the MDR and IVDR better recognise the various types and sizes of manufacturers and the product lifecycle phase. The regulations should provide plausible paths to market for startups with their first product, SMEs and established large players and for both truly novel applications technologies as well as established technologies and device types.

HealthTech Finland would like to bring to the Commission its observations and the experiences of its member companies regarding the current MD/IVD regulations, and to provide targeted suggestions for more efficient, proportionate legislation, without compromising patient safety.

Identified targets for improvement

HealthTech Finland has identified areas possibly benefiting from fine-tuning or more major changes especially in the following areas:

- More proportionate risk classification and conformity assessment, better reflecting the risks related to different types of devices
- Simplified and uniform processes for clinical investigations and performance studies, incl. combination studies (clinical drug trial + MD/IVDs)
- Special mechanisms for novel and innovative devices, as well as orphan devices
- Appropriate level of oversight for well-established technologies and legacy devices with a well-documented safety history
- Reasonable cost level and structure for all actors, but taking into account especially SMEs
- Fair and equal market surveillance, ensuring that non-compliance is not profitable and unjustly rewarded, and compliant actors are not at disadvantage

These areas, as well as some additional identified targets for improvement are analysed in more detail below, and suggestions for practical changes are given, where possible.

Special device groups

Novel and innovative devices

Medical technology is a heterogenous field, and the length of product development cycles varies greatly between device types. Design and testing obviously always needs to be allocated sufficient time in order to be able to produce safe and efficient devices. However, in certain cases, fast-paced translation of research into new devices and patient benefits may be scientifically and technically possible: The path from discovery to IVD devices applications can be short, even only months, as experienced during covid19 pandemic. In addition to the development of new IVD tests, AI applications are also a fast-developing field, possibly producing new product faster than we have previously been used to. Currently, the time need for conformity assessment by notified bodies may in some cases greatly surpass that needed to develop the device.

There is a clear need to establish procedures within the EU similar to e.g. the FDA's Novel and Breakthrough Device programs. These models provide accelerated assessment and close interaction with authorities for the most promising solutions addressing critical clinical needs. A comparable pathway in Europe would improve access to innovation, support the development of European health technology, and strengthen patient safety without compromising quality or regulatory compliance.

Although the possibility for national derogations exist, derogations are intended to be temporary solutions for exceptional circumstances and are granted separately by each member state. Alternative routes to ensure safety but allow lifesaving or healthcare transforming novel devices to reach patients un-delayed, should be explored. Mechanisms that could be used include the use of expert panels to assess clinical evidence, combined with conditional certification with greater emphasis on clinical/performance follow-up and post-market surveillance in the first years on market.

For comparison, HealthTech Finland would also like to refer to the conditional marketing authorization process of medicines by EMA: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation.

Old and legacy devices, well-established technologies

Transition rules have been devised to ensure that devices previously safely used are continuously available to the patients that need them. Although these transition rules have in many cases ensured the transitioning to the MDR (or IVDR), there are still challenges for many manufacturers, despite the devices having a long history of safe use. As stated earlier, especially for up-classified legacy devices previously not needing notified body conformity assessment, the increased costs may prove to be unjustifiable commercially, if no targeted measures are applied.

Any new simplification measures should carefully take to account the various type of legacy products, and how any new regulatory requirements should be applied to them. Special attention should be paid to devices based on well-established technologies, with a long history on the market, and a well-documented safety history, so that unnecessary regulatory burden can be avoided. It should be considered if special mechanisms could be made available for allowing these devices to continue on the market without having to go through full conformity assessment essentially devised for new devices. Such mechanisms could include allowing the NB certification process to concentrate mainly on QMS, with risk-based sampling of less technical files/over larger device groups or categories.

Orphan devices

Special mechanisms are required for orphan devices, both old and new, critically needed for small patient groups, where regulatory costs often cannot be commercially justified. Orphan devices should be considered separately from novel devices, where initial device numbers may be low, but figures may be expected to rise in the long run. For orphan devices, where device numbers needed for patients are predicted to stay low, but constant, the regulatory costs are not only an initial obstacle, but also the continued costs of NB oversight need to be considered.

In addition to costs, also the type of clinical evidence required needs to be considered, as patient populations can be small. Allowing manufacturers and NBs to rely more on post-market real world evidence may be one part of the solution, but legislative clarity and guidance are needed to support the safe application of such procedures. Similar mechanisms are proposed as for novel/innovative devices above, possibly involving expert panels, and with costs at least partially covered by special financial routes.

Costs have increased significantly dure to the MDR and IVDR

In general, additional costs brought on by the MD and IVD regulations are related to the costs of the enhanced third-party conformity assessment process itself (NB fees, and the resources needed for interactions with NBs) as well as the need for resources to run the more complex processes required by the MDR/IVDR. This includes e.g. multiple reporting obligations, more complex and time-consuming processes for applications for clinical investigations and IVD performance studies.

Adding more proportionality and scaling to requirements and the respective conformity assessment process, depending on device type and risk class, will in part help in bringing the cost to a manageable level.

In addition to answering the plea for a more reasonable and proportionate cost level, more predictability of cost structure (and time) for conformity assessment is needed so that manufacturers can plan and prepare accordingly.

Special financial instruments for specific device groups and SMEs

As stated earlier, SMEs struggle with the current costs of the MDR and IVDR, especially NB conformity assessment. For companies of any size, orphan devices may just not be financially viable as commercial products under the MDR/IVDR cost structure.

Notified bodies are already legally required to take into account SME's. However in practice, as a majority of medical device manufacturers are SMEs, and notified bodies need to be financially viable, NBs cannot be expected to subsidise orphan or novel device manufacturers, or SMEs, however significant or life-saving the device may be. Currently, costs for conformity assessment are a significant barrier to initial certification and/or burden for keeping small-volume devices on the market.

For medicines, concessions are in place for SMEs at medicines authorities. **It is proposed that an EU-level financial instrument for medical device and IVD conformity assessment is set up, to allow for SME manufacturers of MD/IVDs of equally important medical devices to be able to benefit from similar treatment as SMEs in the pharmaceutical industry. In addition to SME's, special financial instruments are needed for orphan devices, as well as support for breakthrough device routes.**

Any such new financial and other mechanisms need to take into account the nature of the devices in question, still ensuring an equivalent level of patient protection. Special mechanisms need to be fair, and equally available to manufacturers throughout the Union. In order to ensure the availability of certain devices to patients, also manufacturers outside the Union need to be considered. As conformity assessment is performed by notified bodies located in any member state, regardless of the manufacturer's location, such mechanisms cannot be based on national derogations or national funding.

In addition to compensating for reduced notified body fees, other mechanisms should also be considered. For example, for novel/orphan devices, where limited clinical evidence may be available and/or initial certification could be conditional, the use of expert panels for initial or continued additional oversight could be considered, with expenses covered on Union level.

It should be noted that there may also be financial implications related to uneven implementation of requirements and insufficient market surveillance of non-compliant competitors: there is a feeling within especially SMEs that compliance is not rewarded, and compliant actors may even be at an disadvantage, as non-compliant competitors are still continuing their activities without market surveillance measures being directed towards them.

Qualification, classification and conformity assessment

Conformity assessment routes depend on the risk class assigned to a device, and accordingly, the higher the risk class, the tighter the oversight. However, currently, the differences between class IIa and IIb, or IVD classes B and C are not very big. Especially in the case of SMEs with only one or few products, falling into different device groups and categories, the conformity assessment processes can be very similar, as risk classed based sampling does not reduce the relative amount of technical files sampled, nor is their any other difference in the depth of NB assessment.

Adding more proportionality and scaling to requirements and the respective conformity assessment process, depending on device type and risk class, will in part help in bringing the cost to a manageable level while ensuring that patient risks are not negatively affected. Such scaling could be achieved by targeting both QMS review, and technical documentation review (depth and sampling), as well certification cycle length, taking into account the risk class.

In addition to the need for a more manageable cost level and structure, more predictability of costs (and time) for conformity assessment is needed so that manufacturers can plan and prepare accordingly.

Ensuring that risk classification matches device risks appropriately is also part of ensuring that conformity assessment and related costs are proportional to each device in question. For this, classification rules need to be reviewed. Rules for MDR risk classification (mostly written already for the MDD) do not always fit the reality of modern medical technology. In such cases, classification rules may lead to a higher (or some cases, lower) risk class, not proportionate to the actual risks to the patient.

It is proposed that in case necessary changes to qualification arising in the Call for evidence or elsewhere need a longer time frame to be completed and implemented, the Commission could also proceed with implementing Acts according to either MDR article 4/IVDR art. 3 (qualification) or MDR art. 51/IVDR art. 47 (classification). Below, some specifically challenging areas are discussed in more detail.

IVD risk classification

For IVDs, the IVDR risk classification system is new, and based on IMDRF principles, as is appropriate. The current system is a major improvement from the static, IVDD era, list-based system. The IVDR saw many improvements and added oversight for IVDs, as compared to the IVDD, and for good reasons, as seen e.g. during covid19. However, the IVDR classification rules would benefit from some further fine-tuning, ensuring that classification correctly reflects the risks involved.

There are currently many rules that will make an IVD class C, or even D. Some specific rules exist also for class A. Class B devices are mainly defined by not belonging to the other risk classes, D, C or A. It could be possibly considered, if IVD classification would benefit from some specific rules laying the foundations for classification as class B (or clarifying, what is

not C or higher). Currently, as multiple rules will lead to risk class C, class B is maybe underused. Additionally, for infectious diseases, there is a high risk of an IVD that was not covered by the IVDD lists A or B, to now become class D, which is a huge up-classification. The term 'life-threatening' used in the classification rules should also be defined, as many diseases will eventually be life-threatening, if left undiagnosed and un-treated, but not acutely, making the term ambiguous and difficult to uniformly interpret.

It should also be noted that IVD classification appears to be written with IVD *tests* in mind. The classification rules are not very well suited for other types of IVD devices, such as standa-alone IVD software. Especially rule 5 does not take into account software properly. **A review of IVD classification rules is proposed, especially targeting rules 1 and 3, as well as rule 5.**

Classification rules may never be able to appropriately address every possible case. In cases where the classification rules may lead to overly high or low risk classes, mechanisms need to be in place to timely and efficiently make Union level binding decisions to change the classification where appropriate.

It is proposed that in case necessary changes classification rules in the IVDR need a longer time frame to be completed and implemented, the Commission could also proceed with implementing Acts according to IVDR art. 47 (classification), if classification of certain device types are seen to not reflect the actual risk level.

Too extensive modelling of the IVDR on the MDR?

Many IVDR requirements, e.g. the 4-tier classification system and conformity assessment procedures mirror those of the MDR, with some IVD specific terminology and features such as European reference laboratories added. However, the IVDR still encompasses many elements more suitable for MDs and does not fully take into account the different nature of IVD devices and related risks.

As the MDR and IVDR both have a 4-tier classification system, it is also possibly erroneously assumed that the four risk classes are equivalent in the MDR versus the IVDR. This is subsequently reflected in the respective conformity assessment procedures. Ie. the risks related to a IVD class A are possibly being assumed to being equivalent to MD class I, and IVD class D, e.g. an HIV-test, being equivalent to a class III device, e.g. a class III implant. Sampling for class B and C devices is similar to class IIa and IIb devices, respectively.

But IVDs are not the same as MDs, and IVD risk classes should not be treated equivalently to MDR risk classes, as the related risks are not the same. In this aspect, the MDR and IVDR are not proportionate or coherent. For example, IVD class A sterile devices are treated similarly to MD class I sterile devices, although only the latter will be in contact with the patient, causing any risk of infection, as for sterile IVDs, sterility is typically for ensuring reagent or sample stability and correct functioning of the assay.

It should be carefully assessed what is the level of oversight required for IVDs per risk class, and this does not have to be equally mirrored in the MDR risk classes.

Ther is no going back to the IVD directive, but it should be critically assessed which elements of the IVDR are justified, proportionate to risk, and necessary, and which requirements may be unnecessary regulatory burden, not significantly enhancing patient safety.

Near patient testing (NPT)

Testing is increasingly coming out of the laboratory, closer to the patient, to provide information directly where and when it is needed. However, in practice, there is no clear distinction between NPT devices and other professional use IVDs, or what even qualifies as a near patient testing set-up. The distinction between a laboratory environment and another type of test setting is not clear-cut: for example, is a separate 'satellite-unit/mini-lab' in a ward or physicians office back-room, operated by a laboratory professional, but outside central laboratory premises, NPT, or not?

Risk classification defines the conformity assessment route applicable to the device. From risk class follows the possibility to sample technical files proportionately per device category or group. Conformity assessment of NPTs is currently not proportionate to the device type and risk class. For NPTs, **the IVDR does not allow for sampling in conformity assessment of class B or C NPTs**, as is allowed for other IVD devices of the same risk classes (article 48 point 9). This causes devices which are classified as class C, or even second lowest risk class B, in practice to be treated as strictly as class D devices, regarding sampling.

Near-patient testing is commonly performed in the context of a healthcare organisation's operations, where it is possible to have a suitable quality management system and quality controls in place. NPT operations are typically supervised by laboratory professionals, with appropriate training and backup for non-lab-based NPT users. Self-testing is a totally different case, where lay person users, without training in healthcare or laboratory sciences, perform tests outside of a quality management system or any quality control processes.

The general safety and performance requirements in annex I, (point 19), as well as annex IX, point 5.1 (for technical documentation assessment) combine NPTs and self-tests together, although the risk related to these two very different types of tests are not equal. This approach can be considered incoherent, as well as unjustified and non-proportionate.

It is important that devices intended for near patient testing by healthcare personnel other than laboratory professionals, are designed with the particular user population in mind, and the performance of NPTs should always be evaluated in the intended user group and use environment. However, near patient testing is not in itself a significant risk factor for the patient, which is also mirrored in the IVDR risk classification rules, where unlike self-testing, NPT status does not change the risk class of an IVD (annex VIII, rule 4b). This should similarly be reflected in the conformity assessment process of NPTs, maintaining the respective relationship between risk classification and conformity assessment stringency.

Keeping the NPT-specific design and performance evaluation requirements but treating NPTs equally to other professional use tests of the equivalent risk class in conformity assessment, would reduce costs and regulatory burden for manufacturers, without critically affecting the

level of oversight for these tests, and would be more in line with the respective risks of the devices. Further, more reliance on harmonised standards is called for, which should provide for sufficient level of patient safety, in line with the principles of the NLF legislation.

Companion Diagnostics (CDx)

Companion diagnostic IVD devices are important especially in the rising area of personalized medicine. CDx are typically used in critical areas such as oncology, and in some cases, for relatively small patient numbers. However, actually most IVDs, not only CDx, produce information that is important for correct medication. (e.g. TSH and T3/T4 testing in thyroid disease). Despite this, only devices defined as CDx require an additional assessment (consultation process) by medicines authorities. The consultation process is an additional step in the conformity assessment, costing both money and time, slowing down these devices reaching patients.

It should be carefully assessed if the currently required CDx consultation process by the medicines' authority is both necessary and appropriately applied, and if such patient safety benefits are achieved that can justify the substantial burden of this process. It should also be considered that the costs of the process are forming a barrier to bringing these devices to the market. Thus, the lack of available testing may be causing more medication related risks than the device itself ever would.

NBs are required to have special expertise in CDx. It should be assessed if this would be sufficient, or if there would be alternative ways to add to the safety of CDx devices and respective medicines than the current consultation process. (e.g. via expert panels, scientific advice or training and guidance by EMA, etc.). It should also be assessed whether in practice the current consultation process is in line with the requirements of the IVDR, or whether the current process includes unnecessary elements not exactly required in the IVDR, or overlapping with the notified bodies responsibilities, and that could be simplified.

It is proposed that when possible, the interplay between the medicines' legislation and the IVDR should be examined. It may be more appropriate to answer some CDx related issues through the medicines' legislation.

It is also noted that the definition of a CDx is not uniform between the EU and other jurisdictions, e.g. the FDA, which causes unnecessary confusion. (e.g. devices intended to monitor treatment responses are not CDx in the EU).

Please note that the above suggestion for major changes and simplifications do not necessarily directly apply to the consultation processes for medical devices with ancillary medicinal substances, as this process is still seen as important for patient safety. However, similarly, the high costs of the respective MDR consultation processes are highlighted.

IVDs for genetics and genomics and other *-omics*

Genetic testing-based diagnostics is becoming an everyday part of healthcare, used in many medical areas from blood typing to allergology. The current classification of all genetic testing

as minimum class C does correctly reflect the current applications for genetic testing and related risks of genetic tests and can be considered outdated in light of the current clinical reality of genetic testing. E.g. lactose intolerance and Huntington's disease testing are both classified as class C, which does not correctly reflect the respective risks of these tests.

Classification rules, as well as the respective IMDRF classification principles, should be re-assessed in light of current understanding and common clinical use in the field of genetics and genomics. The classification of genetic testing should be more clearly based on the intended use of the device and the benefits and risks foreseen, instead of technology alone.

The special nature of genetic testing, incl. the use of whole genome/exome sequencing type approaches, producing large amounts of data, as well as in some cases evolving over time, needs to be better taken into account in the IVDR. Similarly to genomics, other types of –omics-based diagnostics (transcriptomics, metabolomics, etc.) should be better taken into account, instead of assuming only 'one test-one disease/diagnosis' type of devices. This should be considered for all aspects of requirements, from performance evaluation to conformity assessment.

Although simpler to handle, also multiplexing, typical for IVD products, should be better taken into account in the IVDR. Especially requirements for conformity assessment of multiplexed devices incorporating tests of different risk classes and types.

Qualification

Qualification as an MD or IVD is key to being regulated via the MDR/IVDR. However, qualification is not always evident, and qualification questions and disputes may arise. A timely and efficient mechanism, involving sufficient practical expertise in qualification matters for solving such cases needs to be devised.

The current so-called Helsinki procedure and the Borderline manual are considered a useful but too slow a route to solving such issues, leaving manufacturers in doubt of the correct qualification for extended periods. This can seriously slow down bringing a new product to the EU market, or even totally stop the process, if manufacturers and investors do not have clarity on the status of the product.

Particularly challenging are cases of medicine-medical device borderline products, where national medicines authorities have priority on qualification and authorities may have vastly differing opinions. As an example, a member company of HealthTech Finland described experiencing challenges with several products, for which medicines authorities -despite the NB certificate and CE-marking - in different member states are taking different opinions on drug or device qualification, making marketing and regulatory compliance complicated, unpredictable and costly.

An efficient joint EU-level process for such cases needs to be established. Similarly, other challenging borderline and qualification issues would benefit from a joint EU-level process, involving regulators from other fields where needed (cosmetics, biocides, food etc.).

Qualification and Classification: MD and IVD software

Intended use, and risk classification according to annex VIII defines the respective conformity assessment process, and the respective costs. For the regulatory system to be fair and even, and for the level of scrutiny to correctly reflect the risks involved, classification rules need to ensure appropriate classification of different types of devices.

MDR classification rules have led to a significant number of software based medical devices to be up-classified to higher risk classes (from I to IIa or higher), leading to significantly increased costs. Very few devices are left in class I.

Although for many devices, up-classification and NB oversight has been appropriate, not all up-classified software-based devices are in practice high-risk, and their use involves significant safeguards. E.g. up-classified devices include in many cases also very simple medical calculators such as BMI, CHA_2DS_2-VASc). Many MD software products which are only intended to be used to provide additional information supporting decision making in non-acute situations but not provide definitive diagnoses or drive clinical management are classified as class IIa, minimum.

MDR rule 11 needs to be further adjusted to more proportionally allow software MDs to extend proportionally over all risk classes, including class I where appropriate. It is proposed that principles described in the respective IMDRF documentation on software should be better included in the MDR/IVDR. Currently MDR rule 11 uses the term 'Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes". It is suggested that rule 11 better take to account the type of intended use of the provided information, similar to what is described in by IMDRF, differentiating between '*driving clinical management*' and '*informing clinical management'*.

Current **IVDR classification rules for software** do not properly allow for classification of IVD software as the rules are mostly aimed at IVD tests and related equipment (instruments, hardware) in mind. Currently, it is unclear if rule 5 can be applied to IVD software at all, to allow for software to be class A at all. A specific IVD classification rule could be considered, similarly to MDR rule 11. Similarly to what is proposed for the MDR rule 11, IVD classification rules for software should take into account the intended use of the device, but also the relative role of the software in the diagnostic process, similarly differentiating between 'driving clinical management' and 'informing clinical management (diagnostic with/without human oversight, guidance, automation of simple calculations etc.). IVD classification for software should allow all risk classes A to D to be used proportionately to the intended use and risk.

In addition to software to be used in relation to various somatic illnesses, qualification and classification of software with applications in the area of mental health and wellbeing should be specifically addressed in the classification rules (e.g. mental health apps). Currently the regulatory status of some of these devices may be unclear, and it may be difficult to determine what applications in this area fall into the medical device definition. (There are initiatives both at WHO and MHRA in relation to this topic, which should be followed closely.)

Medical calculators (MD and IVD)

So-called medical calculators can include simple calculators such as BMI and CHA_2DS_2-VASc. Medical risk calculators are also available for chronic diseases with major public health impact, such as diabetes, cardiovascular diseases, and various other purposes.

The qualification and classification of various medical device software and especially medical calculators should be clearly and uniformly addressed, ensuring consistent qualification and classification, correctly and proportionately representing the medical risks (or lack of such risks) involved. For medical calculators, it is relevant that the scientific background is sound and calculations are performed correctly. However, the use of software for such simple calculations does not bring significant new risks compared to manual calculations. It is of course important that the scientific content is kept up to date (state of the art). However, the current situation where the same simple calculations (e.g. CHA_2DS_2-VASc) are incorporated into several medical device software products means that there are certified repeatedly and in parallel by several notified bodies, which is both inefficient and costly, and does not bring respective increases in patient safety. On the contrary, due to increased costs, healthcare professionals may revert to manual calculations, which increases the risks of errors.

It is proposed that software qualification and classification definitions and rules are amended with additional details to either exclude simple medical calculators from qualifying as medical devices/IVDs, or to classify them as risk class I, similar to solutions adopted in several other jurisdictions (eg. TGA exclusion 14L, FDA, UK MHRA).

Currently, there are medical calculators commercially available that are CE-marked, appropriately assessed by notified bodies, according to their risk class. At the same time, there are many more medical calculators available that are not compliant, offered by various actors either for payment, or for free, or developed by healthcare organisations and professionals themselves. Additionally, there are even many publicly funded projects, where various risk calculators and other medical calculators are developed and offered to both medical professionals and the public. (E.g. risk calculator development in the JACARDI project), without the calculators even being identified as medical devices. This has created a very uneven business environment, not providing incentives for compliant manufacturers. Consistency and coherence are needed to ensure that all medical calculators offered are safe and compliant, and actors are treated equally.

MDs incorporating an IVD

It should be noted that the current scope of the MDR and IVDR may lead to unequal levels of oversight for devices with almost identical intended uses (see IVDR art 1, point 4)

As an example: a regular HIV test would be classified as IVD class D, but an HIV test with an inbuilt sampling part would likely be regulated as a MD, due to direct patient contact (for lack of specific rule, possibly even class I). Although the test part of such a combination device does need to fulfil the IVDR requirements, the risk classification and conformity assessment procedures would supposedly be according to the MDR. As MDR classification rules are not

designed for this type of product, this can possibly lead to a respectively much lower risk class and conformity assessment route not requiring the same level of microbiology expertise at the notified body nor involving a European reference laboratory. (MD notified body with general microbiology expert vs IVD NB, with more specific expertise in HIV testing specifically, +EuRl verification) Possibly even no NB would be required.

Previously, such devices were defined as MD or IVD based on the *principal intended use*, now any direct contact makes these devices MDs. To ensure patient safety, and the equal treatment of manufacturers, the qualification and classification of such devices need to be reassessed, and the appropriate conformity assessment process defined.

IVDR scope: research use only and general laboratory equipment

The IVDR does not apply to: "*products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination*;". It would be beneficial to clarify further in the IVDR what is 'research-use only' or 'general laboratory use', as this is not always self-evident, causing confusion on the market.

Conformity assessment and certification

Third-party conformity assessment is an important part of ensuring device safety and strengthening the conformity assessment processes for medical devices and IVDs was needed, as compared to the IVDD/MDD era. Especially for high-risk devices, notified bodies (NBs) are indispensable.

However, the current system for notified body oversight is considered relatively costly and time-consuming, and at times, not flexible enough to ensure important devices can reach patients needing them in a timely manner. Especially for most IVD manufacturers and many software manufacturers subject to relative up-classification of their products due to the IVDR/MDR, the certification process has proved to be a significant obstacle to market, both for new products, but also for keeping some low- or medium volume products on the market. Thus, any adjustments that can be done to the process that could lessen the regulatory burden and decrease the related costs, without negatively affecting patient safety are welcome.

The following points are highlighted:

- The scope and depth of third-party assessment for each risk class should be carefully assessed, and whether conformity assessment requirements for lower risk classes could be amended. Could the conformity assessment process for class B IVDs be simplified, for example concentrating more on the quality management system, QMS, with less technical file sampling? Could surveillance audits for class B or IIa devices be conducted less frequently?

- Allowing for a **suitable level of sampling of technical files** can significantly reduce the regulatory burden and costs. E.g. it could be considered if sampling could be more widely allowed (see below especially the case for class b and C near-patient testing)
- Although open-ended certificates without end-dates may not be appropriate, **extending the length of certification cycles** for lower to medium risk classes (IVD class B, A sterile, MD class IIa, Is, Ir, Im) could be considered. Additionally, it should be clarified what certification renewal requires, as this should not necessarily need to be equal to an initial NB assessment.
- **Costs.** The MDR/IVDR require notified bodies to take into account small and medium sized enterprises (SMEs) in their fees. However, this has not worked very well in practice, as the majority of manufacturers are SMEs, and the NBs cannot be expected to carry the financial burden for such a system. A joint-EU-level financial instrument is needed to compensate fees for SMEs. (see below for further details.

Conformity assessment and significant changes

In order to ensure that devices pertain continuously to state of the art, changes may need to be made, some of them considered significant, triggering an assessment of the change by the notified body. Changes may arise from vigilance and post-market surveillance, or the manufacturer may wish to add new features or intended uses to the device. Significant changes require notified body assessment to ensure that devices continue to be safe and perform as intended.

However, change notification processes maybe slow, and the related costs high, especially for SMEs. A critical assessment of what is considered a significant change and requires NB assessment should be made. E.g. allowing preplanned changes already preliminarily communicated to the NB at initial/previous certification phase to be excluded from the change notification process, and to be assessed in relation to annual surveillance audits, would decrease time and cost, and add flexibility to the process. Similarly, allowing more changes to be either not considered significant, or for si**gnificant changes to be conditionally accepted, and assessed in more detail a later phase** could be considered for lower risk class devices at least.

Making the change notification process more efficient and predictable would reduce unnecessary delays, ease the burden on both companies and notified bodies and ensure patients gain faster access to best-in-class medical technologies. Regardless of process details, predictability of time and cost is needed, as for the conformity assessment process in general.

Clinical investigations and performance evaluation studies

General

Currently, the wide differences in national legislation and interpretation of EU regulations for clinical investigations (CI) and performance studies (PS) are complicating study applications for multi-centre studies performed in several EU member states and creating an uneven environment for clinical research in the EU. Similarly, application processes for studies combining MD and IVD devices, or devices and drugs, are even more complicated for both sponsors and authorities. Even in one member state, processes may be unnecessarily cumbersome.

A more uniform, preferably single national or EU-level entry point system, is needed, to ensure that such studies can be performed in the EU, ensuring patient safety, while keeping bureaucracy at a reasonable level, thus ensuring that manufacturers are able to bring new innovative devices to the market in a timely manner.

Requirements of the AI Act in respect to devices in the clinical investigation/performance study phase need to be harmonised between the AIA and the MDR/IVDR. A clear route is needed for clinical investigations or IVD performance studies with devices that are also covered by the AIA. Additionally, the EHDS and Clinical trials' regulation need to be taken into account.

Feedback on Clinical strategy

There is also a clear need for a system where manufacturers can get feedback on their clinical strategy as early as possible. In order to effectively plan clinical activities and resources, the manufacturer needs at minimum a general indication of whether the proposed clinical strategy is deemed acceptable or not. Even with the best clinical resources and planning at manufacturers, there is still the risk that NB's will disagree at conformity assessment phase.

To avoid such situations, the possibility for structured dialogue on clinical strategy would be important with notified bodies at pre-submission phase. It is clear that notified bodies cannot provide consultancy. Thus, any clinical strategy discussions as part of pre-submission dialogue would be intended to be high level in nature, and notified bodies would not be expected to provide any specific advice on how to achieve compliance with regulatory requirements. Alternatively, expert panels could also be used for feedback on clinical strategy. Bringing predictability to clinical strategy early in the pre-submission stage (ideally during the early product development phase) would improve the predictability of the entire conformity assessment process and would benefit the industry greatly. Especially important it would be for SMEs and start-ups, where clinical resources and experience may be more limited.

For a more detailed analysis, please see joint position paper by MedTech Europe, AESGP, MedTech &Pharma Platform and COCIR: Clinical strategy as part of pre-submission dialogue between manufacturer and Notified Body - COCIR

IVD performance evaluation studies (PS)

For PS, it is common that sample collection and analysis can happen apart from each other, at different times and locations, possibly even in different countries. However, the IVDR does not properly take this into account in the PS application process. To clarify this situation, the **requirements and application process for study sites using the investigational device (e.g. test) vs. study site responsible for sample collection, should be differentiated**.

It would be beneficial to further define what is considered a performance study, as compared to early phase proof-of concept or biomarker discovery studies. Also, it should be assessed if a system similar to MDR article 82 would be useful to cover unclear cases of IVD studies or whether general national research ethics legislation is sufficient.

IVDR article 58 -1a has posed problematic: "surgically invasive sample-taking is done only for the purpose of the performance study;", as the IVDR does not define surgically invasive sample-taking and member state interpretations on which studies require an application have not been uniform.

Companion diagnostics and performance evaluation studies with leftover samples

Currently, performance studies with leftover samples do not require an application or notification, unless Companion diagnostics (CDx) are used. Why such studies require notification when CDx are used, and what is the purpose of this notification, needs to be addressed. If testing of leftover samples would retrospectively lead to interventions, this is already covered in article 58, and such studies would need an application. **The requirement for a notification for CDx studies with leftover samples only is incoherent and cannot be justified, as no particular higher risk to patients or users can be identified for these studies, as compared to other performance studies with left-over samples.**

Other targets for improvement

Post-market surveillance and vigilance: Removal of unnecessary reporting

Post-market surveillance and vigilance, as well as performance/clinical follow-up are important parts of continued device safety but reports alone do not ensure patient safety or prevent incidents. The current reporting and documentation requirements include overlapping requirements for which the added benefit and safety are unclear. (common elements may be shared in PMS report, PSUR, PMPF, PMCF, SSP, SSCP). Considering the high numbers of reports are also causing a burden to authorities, it would be preferable that a system is created which allows authorities sufficient oversight, without unnecessarily burdening manufacturers. IT should also be taken into account, that in addition to reports received, authorities can always request additional information when needed.

Instead of multiple layers of reporting, it is important that manufacturers can create a working system which best serves their devices and activities, and where vigilance and PMS are appropriately interconnected with risk management and continued clinical/performance evaluation. Competent authorities as well as notified bodies should always be able to request any additional information when needed. **To ensure that both manufacturer and NB/competent authority resources are efficiently used to actually enhance patient safety, it should be carefully assessed which parts of various reporting obligations overlap, and what elements could be combined, excluded or otherwise simplified without losing essential information and device oversight.**

Flexibility in the reporting time lines and technical format could also simplify manufacturer processes, allowing more efficient combining of various EU and non-EU reporting obligations and allowing manufacturers to concentrate on content rather than formalities.

Notified bodies – operations, designation and surveillance

Notified bodies are an important part of ensuring device safety in the EU/EEA. Unfortunately, despite the MDR/IVDR, differences in interpreting and applying MDR/IVDR requirements still exist, as witnessed by manufacturers. Manufacturers as well as European patients deserve a system that is predictable and reliable, and where all notified bodies work to similar high standards and implement the regulations equally. Industry also needs a system for feedback before and during the conformity assessment process. How far this could be done under the umbrella of so-called structured dialogue, or whether other mechanisms are needed, is another issue to be solved.

It is essential that notified bodies operate in a harmonised manner. Strengthening of EU-level surveillance of notified bodies, as well as better enforcing the current regulations nationally should be considered. If non-uniform interpretations are encountered, it should be possible for both manufacturers and notified bodies, as well as designating authorities, to bring these issues forward to EU-level, to ensure that any differences in interpretation and implementation are uniformly handled and the resulting consensus shared with all notified bodies.

In parallel there is the discussion under the AI Act on how so-called regulatory sandboxes should operate. Similarly, for medical devices, a system is needed, where manufacturers, regardless of member state, can get feedback on critical device related issues such as sufficient clinical evidence before conformity assessment. Such mechanisms could include expert panels and/or competent authorities, possibly also notified bodies, naturally acknowledging that NBs cannot consult manufacturers. (See also above, Feedback on clinical strategy, p. 18.)

The burden for joint assessments for NB designation and redesignation should be more equally divided between member states, to allow for a more efficient system to be created, using the best available experts. Although currently the Commission compensates travel expenses and daily allowance to experts, this does not compensate for the working time of the expert before, after and during the joint assessment, preventing authorities from appointing sufficient experts to missions. As a consequence, also designation and scope extension processes of NBs may experience delays, the effects extending all the way to manufacturers.

Extending the NB re-assessment and designation cycles could be considered, if this can cut regulatory burden and costs trickling down to clients. If necessary, this should be combined with stronger EU-level coordination for annual NB surveillance. Instead of extended designation cycles, still involving a new application and a reassessment, designations could be considered permanent/without fixed endpoints, but requiring regular EU-level assessments/ surveillance inspections. Thus, at least bureaucracy could be reduced, but EU-level oversight would still be in place.

It is clear that notified bodies cannot act as both consultants and certifiers of the same medical devices. However, notified bodies are often part of larger, global, organisations, with various activities performed by different entities of the organisation. For this purpose. annex VII, parts *1.1. Legal status and organisational structure* and *1.2. Independence and impartiality* need adjustments to unambiguously describe if and how notified bodies may be part of larger organisational structures, and how activities in other separate legal entities of such structures may or may not be involved with any medical device consulting or other activities. Such requirements need to be applied uniformly to all notified bodies. (1.2.3e , meaning of *linked to* be defined or rather wording to be changed more precise description of allowed and not-allowed organisational structures.).

Responsibilities of economic operators (articles 13 and 14)

The addition of distributor and importer responsibilities and obligations to medical device legislation is a welcome move compared to the directive era, reflecting the important roles of these operators in the internal market. However, the legislation would benefit from better taking into account the huge variability in importer and distributor operators, and the complexity of real-life distribution chains. Currently, e.g. the distributor requirements apply equally to small kiosks and large enterprises with EU-wide distribution activities. Realistically, this may not be possible.

The MDR/IVDR also do not sufficiently identify other significant actors in the supply chain, such as fulfilment service providers or arrangements such as different types of leasing agreements. Some of these issues and roles may be handled in other legislation such as the general product safety regulation (applicable to consumer products only) or the Digital service act, which are not always practical for, or applicable to, all medical devices. Requirements for economic operators should preferably be included in the MDR/IVDR, and either applicable to all types of economic operators, or differentiated further based on device/operator types, such as retail or whole sale, devices intended for lay people or healthcare professionals, etc (similar to what is currently required for traceability, art. 25). Harmonised interpretations, as described in the Blue guide, should be taken into account, as far as possible.

In regard to large globally operating companies, in order to avoid unnecessary bureaucracy and double work in the distribution chain, it would also be useful to separately consider the definition of roles, and the execution of respective obligations such as labelling checks, where import and/or distribution is handled by local representatives of the same corporation. E.g. Company X (outside the EU) is the manufacturer, and import is handled by daughter company, Company X Finland, part of the same corporation, and operating under the same quality management system.

Additionally, the use of, and need for, so-called regulatory importers needs to be clarified, as this is causing confusion on the market.

Article 16

Article 16, including the requirement for a suitable quality management system, is a welcome addition to clarify responsibilities for translation and repackaging. However, in its current form, article 16 rather prevents than enables any such activities. E.g. article 16 unnecessarily causes challenges especially to small language areas, where manufacturers may not want to take of care translations themselves, even preventing access to certain devices. Current requirements for NB certification for re-packaging and other activities under art. 16 are both unclear and impractical.

It should also be noted that article 16 is not proportionate or coherent with article 22 on procedure packs. Article 16 requires NB certification for certain activities such as repackaging, but if repackaging is done for the purpose of placing the same devices on the market together with other devices as a procedure pack, NB certification is not required, unless sterilization is involved.

It is proposed that the requirement for notified body certification in relation to article 16 is either removed or reduced, clarified and simplified. A suitable quality management system should be a reasonable and sufficient requirement for such activities. A notified body certificate should not be required for translations, or simple repackaging, unless there are changes affecting critical issues such as sterility. In all cases where NB certification is deemed appropriate, the details of such certification should be given, and the process involved should be included in annex VII for Notified body requirements.

Art 6 distance sales

Article 6 on distance sales is an important addition, but it is unfortunately written in such a complicated way that years after the date of application, industry and authorities alike still struggle to understand its scope and what is exactly required. Article 6 is especially important for IVDs such as genetic testing services typically offered from outside the EU either directly to consumers, but also to healthcare organisations. However, it is not evident from the current wording if article applies to the use of devices – i.e. should a clinical laboratory offering tests to EU citizens also use CE-marked devices when running tests (they may not be available in other areas), or does article 6 only apply to situations when a laboratory manufacturers their own tests (laboratory-developed tests/in-house production)?

It should additionally be noted that market surveillance measures are very difficult to perform in relation to such actors: a non-compliant article 6 type actor typically would not even have an authorized representative, who the competent authority could interact with. This may leave European compliant actors at a disadvantage compared to non-compliant non-EU-based actors offering such services much cheaper but not being subject to efficient surveillance.

Clarification of article 6 distance sales scope and requirements, as well as harmonisation with requirements of the General product safety and Digital services acts is also required.

EUDAMED

EUDAMED is an important source of information for authorities, the public and the industry itself. An operational, user-friendly EUDAMED database is needed. To achieve a positive effective, and not just add to manufacturers workload, EUDAMED should be easy to use, machine-to-machine transfer of data should be easily achievable, and manufacturers should have easy access to their own data.

It should however be noted that some information currently required by the MDR/IVDR, may be considered trade secrets, or could be easily misinterpreted by the public when viewed out of context. It should be carefully assessed, which information needs to be publicly accessible, and what information should rather be only accessible to authorities and notified bodies. Such information currently causing concern among manufacturers is e.g. the information related to the subcontracting of design and/or manufacturing of the device. Such subcontracting agreements maybe valuable commercial information, which manufacturers would rather not disclose to competitors. Context and format of publicly available vigilance data is also important, in order to avoid misperceptions by laypersons or the healthcare sector.

Alignment of legislation

As stated above, the medical device sector is struggling with the regulatory burden resulting from several different pieces of legislation: in addition to the MDR/IVDR, manufacturers may need to comply with or to prepare for compliance with the AI Act, Data Act, GDPR, GPSR, EHDS as well as environmental legislation The industry, and SMEs especially, face significant challenges including regulatory complexity, fragmentation, enforcement misalignment, outdated rules, compliance burden, and legal uncertainty across legislation. The current landscape requires SMEs to navigate multiple overlapping frameworks simultaneously, creating substantial administrative overhead.

Although HealthTech Finland does not question the need to regulate these areas, it is critical that as far as possible, other applicable EU legislation should be aligned with the MDR/IVDR, especially when third party conformity assessment is required. E.g. the AI Act.

Compatibility with regulations in other jurisdictions, adherence to IMDRF principles, MDSAP

By aligning legislative requirements as much as possible not only within the EU, but also with the respective requirements of other jurisdictions, the lighter the regulatory burden for manufacturers with exports outside the EU.

It is suggested that vigilance and PMS reporting obligations and other documentation requirements should be flexible in form and take into account IMDRF principles, as well as requirements from other jurisdictions, and where possible MDSAP (Medical device single audit programme) allowing for streamlining of processes. This can have a positive effect not only on costs but also make processes more efficient and promote patient safety, as manufacturers can concentrate more on content rather than format.

Clarity of legislative text

The regulations should be written in a clear, unambiguous way, so that if not lay people, at least regulatory professionals are able to understand them. The number of MDCG guidance documents currently needed partially to support and explain the regulations testifies to the MDR/IVDR not yet achieving this. Unfortunately, it seems that being able to read the MDR/IVDR requires extensive experience and training, which especially SMEs do not have.

It is noted that when compared to other EU legislation, e.g. the GPSR, the MDR/IVDR texts are particularly complicated and complex. The regulation text contains numerous cross-references to other sections and articles, making it difficult for the reader to understand a specific requirement. To fully understand the requirements for a single issue, the reader must frequently navigate across multiple different parts of the regulations. Although some of these issues may be unavoidable due to legal technicalities, some amount of clarification would be greatly beneficial to all affected parties. Also, offering modern technical tools for easier navigation of the complex legal text should be considered.

For an example of a particularly challenging part of the regulations, please see comment above, for article 6, distance sales.

Strengthening regulatory literacy

Overly complex regulations have been identified as a significant obstacle for innovations, and HealthTech Finland supports finding simplification measures to the MDR/IVDR. Additionally, HealthTech Finland would like to highlight the significance of strengthening the level of regulatory literacy in the sector.

Regulatory literacy– the ability of innovators and other actors to understand and navigate regulatory frameworks – is foundational to the success of any innovation ecosystem. Without it, even the most promising innovations risk being delayed, misaligned with market requirements, or abandoned altogether. This is especially true for startups and SMEs, which often lack the internal resources to interpret complex and fragmented regulatory

environments. In certain other areas, such as pharmaceuticals, regulatory knowledge is much more deeply rooted into the operating culture and educational system of the sector. The medical device sector is more heterogenous, and medical device regulatory training has not yet become an inherent part of education in the health technology related disciplines (medicine, biomedical sciences, engineering etc).

Early-stage regulatory guidance—delivered in a digital, accessible, and scalable format—can dramatically accelerate time-to-market and reduce costly missteps. Systematic support for regulatory understanding is called for. In addition to more traditional education, training and guidance documents, digital tools (regulatory technology, 'RegTech') may also be an efficient way to support actors in acquiring the regulatory literacy to successfully move forward with their innovations. For example, digital tools (e.g. Entries) have already been used by European Digital Innovation Hubs to provide such guidance free of charge to SMEs and public actors. These tools do not replace regulators or consultants but can complement them by democratizing access to regulatory know-how.

HealthTech Finland asks the Commission to **support the development and deployment of digital regulatory guidance tools** and to encourage the integration of regulatory literacy into national innovation strategies of member states.

Market surveillance to ensure a level playing field

Lack of appropriate market surveillance creates an unlevel playing field, where compliant manufacturers and other actors are at a disadvantage. Especially in the area of software and AI-based medical devices, compliancy is disappointingly not bringing manufacturers the advantage that has been expected. Competitors and healthcare institutions alike are producing cheaper medical device software which does not fulfil regulatory requirements, and appropriately CE-marked devices are losing tenders as procurement of non-compliant devices continues. This situation may have serious consequences for innovation and bringing safe compliant devices to the market, as well as eroding manufacturer's trust in the regulatory system.

Competent authorities need to have sufficient resources, expertise and efficient legal tools for both guidance and surveillance. In addition to competent authorities individually performing market surveillance, **EU-level coordination needs to be strengthened**. Enforcement of the MDR/IVDR needs to be fair and equal between member states, and market surveillance measures need to be coordinated, where appropriate. Also, there should be a coordinated approach to any market surveillance measure following updates to the borderline manual: if the borderline manual is updated causing market surveillance measures to be initiated in one member state, equal measures should be implemented in other member states for equivalent products. Currently, this does not seem to be the case, e.g. in the case of widely available medical calculators.

Market surveillance of economic actors needs to be strengthened. Currently, all market surveillance authorities do not seem to have sufficient tools to efficiently react to cases where economic actors do not fulfill their obligations according to articles 13 and 14 (e.g.

regarding compliance checks, vigilance reporting or traceability), in cases where the actual devices in question are not suspected to be non-compliant.

It is suggested that the legal tools for market surveillance and sanctions in member states are harmonised as far as possible. Additionally, the JAMS, joint action for market surveillance project under the EU4Health programme should be continued, and market surveillance cooperation established under JAMS should be made a permanent part of medical device market surveillance actions.

Market surveillance of non-EU/EEA actors is not sufficient. Currently, EU-manufacturers are under stricter surveillance than non-EU manufacturers. In practice, non-EU manufacturers are only inspected indirectly via their authorised representatives through documentation reviews, and even those are relatively rarely performed. It seems that most competent authorities inspect non-EU manufacturers under their responsibility on-site very rarely, if not at all. For lowest risk class (class I, or A) devices not needing NB assessment, no on-site inspections or audits may thus ever be performed. This may be partly do to resource constraints, and lack of a clear system to cover costs. **It is proposed that a clearer mandate to inspect non-EU manufacturers on-site should be given, as well as devising a mechanism to cover costs.** Inspections may be considered the responsibility of the competent authority where the authorised representative resides, but additionally a joint system for non-EU inspections could be devised in order to level the burden among authorities. As notified bodies do visit manufacturers on -site, non-EU/EEA inspections by CAs could be mainly targeted at manufacturers of class I/class A devices, as well as legacy devices not yet under notified body surveillance.

Sufficient expertise and resources for authorities to support industry

The regulatory landscape for medical devices in the EU has been in continuous change for almost a decade, creating a very unstable and volatile system, where manufacturers and other actors, and even regulators, struggle to keep up with current and upcoming requirements. There is a strong need for centralized, coordinated information and training in member states as well as for more coherent medical device /health technology policies at national and EU level.

In many cases, the best knowledge of MD/IVD regulatory issues is currently to be found within the competent and designating authority, as the CA/DA is also actively involved in the EU-level medical device coordination group (MDCG) and its working groups. HealthTech Finland would like to emphasize that the competent authorities (CA) for medical devices and IVDs need to have sufficient resources, expertise and efficient legal tools for handling applications and market surveillance, but also resources for guidance to actors, as well as resources for close cooperation on EU-level to ensure harmonized implementation.

Under-resourced authorities mean longer handling times for applications (e.g. clinical investigations), less resources for advice and guidance, and unequal and insufficient market surveillance, allowing for uncompliant, unsafe devices to continue on the market.

To support national competent and designating authorities, and to ensure EU-level harmonisation and cooperation, also the EU level governance structure of medical devices needs to be strengthened, with sufficient permanent staff and expertise.

Final remarks

HealthTech Finland appreciates the possibility to comment on the regulations and hopes that these comments are of help to the Commission when planning both the necessary short-term targeted changes and simplifications as well as for the more long-term more extensive changes to the MDR and IVDR.

HealthTech Finland hopes that this initiative will in the long run increase innovation in the EU and lead to better and more cost-efficient health care, as well as increased economic growth and employment within the EU. It is also important the regulations are reformed to ensure that patient access to small-volume orphan devices is maintained and improved, as well as solutions to still unmet medical needs are advanced, as Commissioner Várhelyi has accentuated. HealthTech Finland along with our member companies continues to strive for these goals while we hope the regulatory framework can be further improved to better support the efforts of all involved actors in the sector.