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Subject:	COMMISSION STAFF WORKING DOCUMENT Cost savings *Accompanying the document* Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

Delegations will find attached document SWD(2025) 1050 final.

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COMMISSION STAFF WORKING DOCUMENT

Cost-savings

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

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Glossary

Term or acronym	Meaning or definition
CDx	Companion diagnostic
CE	Conformité Européenne
CTR	Clinical Trial Regulation
EMA	European Medicines Agency
EU	European Union
EUDAMED	European Database on Medical Devices
IFU	Instructions For Use
IMDRF	International Medical Device Regulators Forum
INN	International Nonproprietary Name
ISO	International Organization for Standardization
IVDR	*In Vitro* Diagnostic Medical Device Regulation
JAT	Joint Assessment Team
QMS	Quality Management System
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
MDSAP	Medical Device Single Audit Program
NB	Notified Body
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Surveillance
PMPF	Post-Market Performance Follow-up
PSUR	Periodic Safety Update Report
SME	Small and Medium-sized Enterprises
SSCP	Summary of Safety and Clinical Performance
SSP	Summary of Safety and Performance
SWD	Staff Working Document
TD	Technical Documentation
WET	Well-Established Technologies

1. INTRODUCTION: POLITICAL, LEGAL CONTEXT AND OBJECTIVES

The European medical technology sector is a cornerstone of EU health systems and industrial competitiveness. Europe is home to over 38,000 manufacturers, 90% of which are small and medium-sized enterprises (SMEs) and is the second largest market in the world following the US[1]. The sector contributes significantly to EU innovation, employment, and exports, while providing patients and healthcare professionals with life-saving and life-enhancing technologies.

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) were adopted in 2017. The Regulations aim to "establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation" (MDR/IVDR recital 1) and further align it with international practices. The Regulations strengthened clinical and performance evidence requirements, oversight of notified bodies, transparency tools, and post-market surveillance, among other topics.

During the implementation and transition to the Regulations, various issues were observed including bottlenecks in notified body capacity, high compliance costs for SMEs, duplication of reporting, and uneven uptake of digital tools. Due to implementation challenges, amendments to the Regulation's **transitional provisions** were necessary to mitigate the risk of possible shortages affecting the supply of medical devices to patients and healthcare systems. The **MDR** transitional period was extended across all device classes, subject to several conditions: to December 2027 for high-risk devices and December 2028 for medium risk devices[2]. Similarly, **the IVDR** transitional periods were extended twice[3,4] and currently run until December 2027 for high-risk IVDs, December 2028 for medium-risk IVDs, and December 2029 for lower-risk IVDs, under conditions akin to the MDR. The modules of the European database on medical devices (**EUDAMED)** are also being rolled out and made mandatory for use gradually, in order to mitigate the consequences of development delays[5]4. In addition, an **advance warning mechanism for supply interruptions and discontinuations** was introduced[6,7]. The Medical Device Coordination Group (MDCG) has endorsed various guidance to support the implementation of the Regulations. Still, based on experience and on the evidence collected through the targeted evaluation of the Regulations[8], it has emerged that the regulatory system would benefit from a more structural simplification of the Regulations.

In view of the challenges encountered in transitioning to the new requirements and to respond to the calls for urgent action from the European Parliament[9], the Council[10] and a large number of stakeholders, the Commission brought forward the planned targeted evaluation[11] of the Regulations to 2024[12]. The targeted evaluation assessed the effectiveness, efficiency, relevance, coherence and EU added value of the Regulations. The evaluation also focused on the availability of devices in the EU (including 'orphan devices' and devices for small populations), on the development of innovative

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[1] MedTech Europe, *Facts & Figures 2024*, MedTech Europe website.
[2] Regulation (EU) 2023/607, OJ L 80, 20.3.2023, pp. 24–29, ELI: http://data.europa.eu/eli/reg/2023/607/oj.
[3] Regulation (EU) 2022/112, OJ L 19, 28.1.2022, pp. 3–6, ELI: http://data.europa.eu/eli/reg/2022/112/oj.
[4] Regulation (EU) 2024/1860, OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj.
[5] Refer to footnote 4.
[6] Refer to footnote 4.
[7] Manufacturers must notify relevant competent authorities, health institutions and downstream supply chain actors of potential supply issues or cessations of certain devices where there is a risk of serious harm to patients or public health (See further Section 4.1.1.3)
[8] [Placeholder for SWD targeted evaluation, SWD(2025)1051]
[9] Texts adopted - Urgent need to revise the medical devices regulation - Wednesday, 23 October 2024
[10] Necessary reforms in the Medical Device and In vitro Diagnostic Medical Device Regulations, 5 December 2024
[11] Refer to footnote 8.
[12] Article 121 of the MDR indicates that an evaluation report must be finalised by 27 May 2027. Those activities have been brought forward by at least three years.

devices, and on the costs and administrative burdens for operators, especially SMEs. The targeted evaluation showed that while the Regulations do raise safety standards, there are proportionality challenges, with high regulatory hurdles hampering EU businesses' innovation in the EU and their competitiveness at global level. These burdens risk undermining innovation and competitiveness, resulting in decreased availability of devices and ultimately having a negative impact on patient care.

The proposal also supports the competitiveness of the EU industry where the environment is strongly protected against pollution. MDs and IVDs need to comply with Union legislation in this area, in particular, the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or applying without prejudice to the provisions of the Batteries and Waste Batteries Regulation and the Packaging and Packaging Waste Regulation. Thus, the proposed revision is consistent with the European Commission's objectives to achieve climate neutrality set out in the EU Climate Law and the Union's Strategy on Adaptation to Climate Change, and more broadly with the 'do no significant harm' principle. Furthermore, the proposal aligns with the proposal of digital product passport by introducing the possibility of digital labelling which will contribute to the reduction of paper use and contributing directly to climate neutrality.

Further to the reports of Mario Draghi[13] and Enrico Letta[14], the need for regulatory frameworks that facilitate competitiveness, resilience and the EU's strategic autonomy has become a key priority for the European Commission. The European Commission's guidelines for 2024-2029[15] also include a strong focus on reducing administrative burdens stemming from EU rules and simplify their implementation. This was reiterated in the Commission's Competitive Compass[16] for the EU, which includes as part of its horizontal enablers, among others, the simplification of the regulatory environment and the reduction of burden and further outlined in the Commission's implementation and simplification agenda[17]. Moreover, the European Commission's Strategy for European Life Sciences also highlights the need to address challenges such as fragmented funding and innovation systems, regulatory complexities and slow market uptake to help Europe regain its position as a global life sciences leader, driving innovation, economic growth, and job creation[18].

The targeted revision responds to these aims to streamline and future-proof the regulatory framework by reducing the administrative burden, enhancing predictability and making it more cost-efficient and proportionate, while maintaining its overall architecture and preserving a high level of public health and patient safety. The general and specific objectives of the Regulations remain unchanged (see Revised intervention logic, Staff working document on the targeted evaluation). The targeted revision does not aim to alter these objectives but to adjust and refine the framework so that those original objectives can be better achieved, in particular in ensuring a high level of protection of health for patients and users and to ensure a high level of transparency on medical devices for all actors and citizens.

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[13] European Commission website, *The Draghi report on EU competitiveness*, September 2024.
[14] Enrico Letta, *Much more than a market – Speed, Security, Solidarity*, April 2024.
[15] Ursula von der Leyen, *Europe's choice, Political guidelines for the next European Commission 2024−2029*, July 2024.
[16] A Competitiveness Compass for the EU, COM/2025/30 final.
[17] A simpler and faster Europe: Communication on implementation and simplification, COM/2025/47 final.
[18] Choose Europe for life science: A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM/2025/525 final

2. MAIN ISSUES AT STAKE

2.1. What is/are the problems and what are their drivers?

Experience with the implementation of the MDR and IVDR, as presented in the staff working document (SWD) on the targeted evaluation[19], demonstrates that, while the Regulations have strengthened safety and performance requirements, a range of structural inefficiencies, duplications, disproportionate obligations and divergent interpretations of the requirements have emerged. These unintended consequences have contributed to decreased availability of devices, longer certification timelines, higher compliance costs and uneven practices across the internal market. These challenges are hampering the EU's competitiveness at global level and affecting patient care.

The main problem areas can be grouped as follows:

- **Evidence generation**

The framework places extensive emphasis on clinical and performance evidence, but in practice the requirements have proved disproportionate for lower-risk devices and well-established technologies (see also the SWD on the targeted evaluation[20], sections 4.1.1.2. and 4.1.1.5.). The current rules restrict the use of evidence from equivalent devices, information from various types of literature, or non-clinical or pre-clinical data. This has made the use of equivalence difficult to operationalise and led to duplicative clinical investigations even where sufficient evidence already exists. Moreover, the authorisation of performance studies and clinical investigations is fragmented across Member States, with divergent procedures, timelines and fee structures. This results in duplicated submissions and high costs even for low-risk studies. Emerging evidence sources, such as *in silico* models and validated computational data are not yet fully recognised, creating a regulatory lag relative to technological and scientific advances.

- **Conformity assessment procedures**

Conformity assessment under the Regulations is procedurally dense and has limited proportionality. Obligations such as technical documentation sampling, validation of summaries of safety and clinical performance (SSCPs) for medical devices or summaries of safety and performance (SSPs) for IVDs, and repetitive post-market documentation apply not always proportionately across risk classes. Notified bodies may interpret legislation differently from the manufacturer and among each other, generating uncertainty for manufacturers, inconsistent workloads for notified bodies and disproportionate costs (see also the SWD on the targeted evaluation; sections 4.1.1.2. and 4.1.1.5. under effectiveness and 4.1.2. under efficiency).

- **Post-market and surveillance obligations**

The Regulations introduced new periodic reporting duties, notably the periodic safety update report (PSUR) and post-market clinical follow-up (PMCF)/post-market performance follow-up (PMPF) requirements. In practice, manufacturers must produce multiple overlapping documents (post-market surveillance (PMS) Plan, PMCF Plan, PMCF Evaluation Report), often containing the same information (see also the SWD on the targeted evaluation[8], sections 4.1.1.5. under effectiveness and 4.1.2. under efficiency). The frequency and scope of PSUR updates and notified body validation obligations have proven disproportionate, particularly for stable technologies with a history of safe

[19] Refer to footnote 8.
[20] Refer to footnote 8.

use. Parallel assessments of serious incidents by competent authorities and notified bodies add further duplication.

- **Notified body oversight of maintenance of certificates**

The system relies on periodic re-certification and annual surveillance audits irrespective of risk profile or compliance history. This "one-size-fits-all" approach generates administrative peaks at re-certification time for both manufacturers and notified bodies, diverting resources from new certifications (see also the SWD on the targeted evaluation[21], section 4.1.2. under efficiency). Unannounced audits are conducted on a fixed schedule rather than triggered by risk signals, providing limited added value for consistently compliant operators. Change management processes remain unpredictable, with no agreed criteria for "substantial changes" (see also SWD on the targeted evaluation[22], section 4.1.1.5.) or pre-approved change-control plans. This results in divergent practices and unnecessary notifications.

- **Cross-cutting procedural fragmentation and lack of coordination**

Differences in national procedures for study authorisation, vigilance reporting and qualification decisions continue to fragment the internal market. The absence of a robust qualification mechanism leads to divergent interpretations on whether borderline products fall under the MDR/IVDR or other frameworks. Similarly, classification disputes are often resolved by national authorities without coordinating with each other (see SWD on the targeted evaluation[23], section 4.1.1.1). This undermines legal certainty and smooth operation of the single market. Moreover, the designation, monitoring and re-assessment of notified bodies involve repetitive steps and overlapping activities, consuming significant administrative capacity at national and EU level (see SWD on the targeted evaluation[24], section 4.1.1.2).

- **Limited support mechanisms and predictability for innovators**

Unlike other major jurisdictions, the EU framework lacks structured, early-stage scientific advice and pre-submission dialogue mechanisms. Manufacturers, especially SMEs, face uncertainty regarding evidence expectations and conformity assessment strategy, often resorting to external consultants at substantial cost (see also the SWD on the targeted evaluation[25], section 4.1.1.2.). This absence of coordinated advice and structured dialogue contributes to late identification of deficiencies during conformity assessment and repeated review cycles.

- **International misalignment and competitiveness challenges**

Finally, whilst alignment with international frameworks such as International Medical Device Regulators Forum (IMDRF) is high, limited alignment with Medical Device Single Audit Program (MDSAP) constrains the EU's global competitiveness (see also the SWD on the targeted evaluation[26], section 4.1.1.3. under effectiveness and section 4.1.3. on coherence). Duplication of audits and divergent evidence expectations impose additional compliance costs for manufacturers seeking to market devices internationally.

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[21] Refer to footnote 8.
[22] Refer to footnote 8.
[23] Refer to footnote 8.
[24] Refer to footnote 8.
[25] Refer to footnote 8.
[26] Refer to footnote 8.

2.2. How likely is the problem to persist?

Without targeted regulatory simplification, these structural inefficiencies are likely to continue. The Regulations are directly applicable with limited administrative flexibility. Most obligations, including audit frequency and evidence thresholds are embedded in law, leaving little scope for harmonisation through experience or guidance alone.

These inflexible requirements, combined with divergent practices as to the extent of assessments, will continue to delay certification and result in high costs, particularly for SMEs, orphan and breakthrough devices.

Fragmented national procedures qualification, classification, vigilance and other aspects of implementation of the Regulations create persistent divergence that cannot be resolved without legislative clarification or EU-level coordination mechanisms.

Certification and post-market reporting obligations are cyclical and tied to fixed frequencies in the Regulations. Without amendments, these will continue to impose repetitive administrative workload regardless of actual risk or performance.

The lack of formalised early-interaction tools (structured dialogue, joint scientific advice) limits learning and convergence between manufacturers and notified bodies; experience shows such tools have not been put in place spontaneously due to absence of legal basis and mechanisms to manage possible conflicts of interest.

Finally, international fragmentation will persist unless the legal framework explicitly enables reliance and cooperation mechanisms with other regulators.

Overall, the status quo is unlikely to improve spontaneously. While more experience with applying the Regulations over time may somewhat improve the efficiency of some processes, the structural inefficiencies and lack of proportionality stemming from the Regulations themselves will remain. Further explanation in the form of guidance is also insufficient to address the issues stemming from the Regulations themselves. Without intervention, the combination of high fixed compliance costs, limited predictability, and uneven implementation will continue to hinder innovation, strain the regulatory system’s capacity, and slow patient access to safe and performant devices in the Union.

3. PROPOSED MEASURES AND THEIR ESTIMATED COST-SAVINGS

Overview of simplification measures

The targeted revision of the MDR and IVDR aims to ensure that the Regulations' original regulatory objectives to "establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation" are achieved in a manner that is efficient, proportionate, and coherent. It does not imply a lowering of standards but rather a simplification and a shift toward more risk-based and data-driven approach through targeted measures, which preserve a high level of protection while improving the system's functionality.

Moreover, these measures are contributing to the original general and specific objectives of the Regulation, in particular the two general objectives to ensure a high level of protection of health for patients and users and to ensure a high level of transparency on medical devices for all actors and citizens. By eliminating unnecessary administrative burden and enhancing coordination among regulatory actors, the revision would support the timely availability of safe and innovative medical technologies across the Union and reducing the risks to patient safety and health related to discontinuation of devices and limited availability of innovation.

Simplification under this proposal operates along several complementary dimensions reducing redundant requirements, improving proportionality, strengthening coordination, and enhancing predictability so that regulatory oversight becomes more data-driven, consistent, and focused on areas of highest public-health impact.

Simplification actions fall broadly into four mutually reinforcing types, each contributing to a more predictable, coherent, and innovation-friendly regulatory environment.

Simplification type 1: More emphasis on risk-based rather than fixed frequency assessment approach

Simplification can be achieved by shifting certain conformity-assessment activities from fixed and cyclical to a more flexible, risk-based approach, where activities are carried out when warranted and to the depth appropriate for the specific case. For example, the current annual technical-documentation sampling for class IIa and IIb non-implantable devices, as well as for class B and C IVDs, would be replaced by targeted, for-cause assessments. Similarly, the automatic yearly surveillance audit cycle would be extended to every two years where there are no identified concerns.

By lightening the regular administrative workload from fixed frequency processes for both manufacturers and notified bodies, the move to more targeted activities would generate measurable cost savings associated with the preparation and assessment of documents and performance of audits. This would be particularly beneficial for SMEs, which are disproportionately affected by heavy administrative requirements. At the same time, it enables notified bodies, manufacturers, and where relevant competent authorities to concentrate their efforts on cases that present higher risk or emerging concerns, rather than distributing resources across files that pose little or no issue.

Simplification type 2: More appropriate differentiation between lower and higher-risk devices

Several measures propose to reduce unnecessary administrative burden on certain lower risk devices for which specific needs have been identified, better reflecting the risks associated with their use (and when applicable, based on their safety history). The purpose is that the resources of manufacturers, notified bodies and competent authorities would be more focused on higher-risk activities where

more oversight is really needed, while maintaining minimum standards for lower risk devices overall, in line with the objectives of the regulations. This includes, for example, the introduction of the definition of well-established technologies and certain exemptions for them, adjustment of classification rules notably for software, removal of authorisation or notification requirements for certain performance studies, removal of obligation for clinical investigations for class IIa implantable devices, removal of notified body oversight for class A sterile IVDs and for class I reusable surgical instruments, provided they comply with standards or common specifications, or greater distinction in the extend of technical documentation sampling between class B and C IVDs.

These proposals would result in significant reduction of burden on the manufacturers, as well as time saving for notified bodies and competent authorities, and allow a redistribution of resources ultimately focusing on higher risk devices and activities. These measures would greatly benefit SMEs as they are particularly active in the area of low-risk devices.

Simplification type 3: Reducing burdens and redundancies in processes

Simplification also addresses burdensome processes and procedural overlaps that create disproportionate efforts or duplication in conformity-assessment and oversight. For example, re-certification that currently results in a heavy review by the notified body and a re-issuance of certificates is proposed to be replaced by a more focused and limited periodic review without the need to re-issue the certificate. The management of changes is also proposed to be streamlined with the use of pre-determined change control plans covering several changes at once, as opposed to their individual assessment. To take another example, currently serious incidents are reviewed by both competent authorities and notified bodies. The proposal would reduce this overlap by requiring the notified bodies to review only a limited subset of the most critical serious incidents.

A special case of this type of simplification is the reinforcement of the EU's role in internationalisation, through reinforced participation in the IMDRF and the use of reliance mechanisms such as MDSAP. The EU's contribution to IMDRF and MDSAP would promote regulatory convergence, reduce duplicated audits, and enhance the global competitiveness of EU manufacturers.

Simplification type 4: Improving legal certainty and predictability

There are two ways in which the proposal aims to provide more legal certainty and predictability. Firstly, the proposal includes clearer definitions or criteria, for example for well-established technologies and for breakthrough, and orphan devices. It also includes clearer and more explicit descriptions for reliance on equivalence or use of methods such as *in silico* or other new approach methods, on which there can be currently different expectations between manufacturers and notified bodies.

The second way of increasing legal certainty and predictability is the introduction of mechanisms through which questions on individual cases can be resolved. This includes strengthened mechanisms to resolve issues of qualification or classification of devices, or the possibility for manufacturers and notified bodies to raise disputes with the authority responsible for notified bodies regarding issues during a specific conformity assessment procedure. Moreover, there are proposals for support mechanisms to manufacturers such as joint scientific advice including both scientific and regulatory experts, and enhanced provisions for structured dialogue between the manufacturer and notified body prior to the submission of the application. Through these processes, the manufacturer would have greater clarity upfront about what would be expected during conformity assessment. The measures are also in line with the specific objective of the Regulations to increase the involvement of external scientific and clinical expertise.

This legal clarity and predictability are expected to yield indirect but substantial simplification benefits by reducing procedural delays, legal and consultancy costs, and uncertainty for innovators, ultimately lowering costs and reducing time to market. By ensuring consistent implementation across Member States, it would also reinforce the functioning of the single market.

Overall, the simplification measures proposed in this targeted revision of the Regulations seek to make the regulatory framework more proportionate, predictable, and innovation-friendly, while maintaining high levels of safety and performance. By reducing reporting burdens, streamlining conformity-assessment and oversight, enhancing legal certainty, and modernising regulatory cooperation, the revision supports the general and specific objectives of the Regulations, as well as the priorities of the Commission set out in the Competitiveness Agenda and SME Relief Package and strengthens the EU's global leadership in medical device regulation.

This SWD analyses the proposed simplification measures and quantifies cost savings, where possible. For each measure, a short description is provided followed by a quantitative or qualitative summary of the estimated cost savings. Annex I provides a summary of stakeholder feedback. Annex II of this document provides a summary table of the measures with the estimated cost saving where possible, type of simplification they provide, and the actors benefitting from them. Annex III provides the base distributions utilised for the calculations, whilst Annex IV contains detailed calculations for each quantified measure.

Proposed measures

3.1. Non-clinical and clinical data requirements

3.1.1. Use of equivalence, real world evidence, in silico and other methodologies

The revision clarifies that the term *clinical data* used for medical devices encompasses not only data generated from the device itself but also relevant data from an equivalent device, from a generic device group or from literature. Manufacturers would no longer be required to hold a contractual agreement granting access to the equivalent device's full technical documentation if equivalence can be scientifically demonstrated on the basis of public or published information. In addition, the equivalence criteria are broadened by the addition of "similar" to the existing definition of generic device group[27]. This would permit the broader use of equivalence claims, improving proportionality and regulatory flexibility. The need to allow for greater flexibility in the definition of equivalence, and therefore in the evidence required, was highlighted in the call for evidence.

The proposal also aims to acknowledge an increased reliance on the use of non-clinical or *in silico* evidence, including bench testing and computational modelling. This codifies the possibility to rely on validated modelling approaches as well as other forms of modern methodologies alongside existing practices. In the call for evidence, some stakeholders supported broader use of non-clinical evidence, real-world evidence and *in silico* methods.

These proposed measures remain in line the specific objective of the Regulations of strengthened requirements for clinical evidence. The measures acknowledge recent developments in scientific evidence generation, also recognized in other markets, and the special context of certain devices (e.g. registries in the context rare diseases, etc).

In addition to directly reducing costs for generating new clinical data, these changes are expected to generate further efficiencies. Broader acceptance of alternative evidence may also shorten the pre-market phase by several months. At the same time, there should be fewer disagreements or misalignment of expectations between manufacturers and notified bodies with regard to acceptability of the alternative methodologies, reducing the number of clarifications and additional information required. Competent authorities are also expected to carry out fewer assessments of clinical investigations where the revised framework allows conformity to be demonstrated through alternative evidence sources. This contributes to a more proportionate use of regulatory resources while maintaining a high level of oversight.

[27] 'generic device group' means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Cost savings:

- Stakeholder and expert inputs indicate that the cost of generating clinical evidence ranges from **€125,000 - €1.5 million** for medical devices and between **€200,000 - €300,000** for IVDs. Allowing greater reliance on equivalence, real-world data and non-clinical evidence enables a portion of packages to reduce costs, particularly those for modified devices as opposed to new devices.
- Based on an estimated 5,300 clinical-evidence packages/year and differentiated adoption rates for new vs modified devices, the annual cost savings are estimated at an average of **€245 million per year.** A large share of these savings are for modification of devices where the above methodologies are more often applicable compared to new devices.

Detailed analysis can be found in Annex IV - Table 1

3.1.2. Removal of mandatory clinical investigations for class IIa implantable devices

Under the current MDR Article 61(4), implantable devices (including class IIa implantable devices) are presumed to require clinical investigations unless it is a modification of an already marketed device of the same manufacturer and equivalence between these can be demonstrated. In practice, this creates a default investigation requirement even for low-risk implants (e.g. dental screws, braces, etc.) where post-market and literature evidence already exist.

It is proposed to remove this default requirement for clinical investigations of class IIa implantable devices. Manufacturers would remain responsible for demonstrating and justifying that the available evidence is appropriate during the conformity assessment, and the requirements for post-market surveillance, surveillance and vigilance remain unchanged. However, clinical investigations would only be carried out in those cases where already available clinical, literature or other non-clinical evidence is not sufficient. This is expected to reduce the number of clinical investigations manufacturers need to design and conduct for these relatively low-risk devices, while maintaining the option to perform them investigations where it is essential.

Overall, this step towards aligning the level of evidence requirements with the risk class of the device, as intended under recitals 63–66 of the MDR, enhances regulatory proportionality and frees resources for genuinely higher-risk or novel technologies where new clinical investigations add value. In addition, competent authorities would face fewer clinical investigations to assess and approve, supporting more efficient use of regulatory capacity.

Cost savings:

- The cost of a class IIa device clinical investigation can be estimated at around **€500,000** with typically around 50 patients enrolled. Around 40 such clinical investigations are estimated to take place in the EU per year.
- This gives an aggregate EU-wide estimated savings potential of **€20.6 million per year** for this measure.
- Further savings can be expected from faster access to market of these devices, as clinical investigations require a significant time investment.

Detailed analysis can be found in Annex IV – Table 2

3.2. Performance studies and clinical investigations processes

3.2.1. Authorisation and notification of performance studies

The revision aims to simplify the requirements for certain low-risk non-interventional performance studies, by removing the obligation for authorisation of the study by Member State authorities or notification of the study to them. This namely concerns studies with low-risk studies involving surgically invasive specimen taking, such as those involving venous or capillary blood draws from non-vulnerable individuals and studies involving companion diagnostics using leftover samples. This aligns the level of regulatory scrutiny with the actual risk to participants and avoids disproportionate administrative effort for studies that pose negligible risk. The sponsors would face a significantly reduced administrative and procedural burden, as they would no longer need to prepare full authorisation dossiers or submit notifications for studies with minimal risk. At the same time, national competent authorities would save resources by processing fewer applications or notifications, allowing them to focus oversight on higher-risk or more complex studies.

Cost savings:

- For performance studies using routine blood draws, using data from authorities on the number of requests and estimations from industry, about 7 such studies can be estimated to take place in the EU per year with an average number of between 4-5 Member States per study. Taking into account manufacturer administrative costs and fees from the authorities, a total saving for sponsors of around **€200,000** per year can be expected from removing the authorisation requirement. It would also save about **€76,000** in national competent authority resources.
- For notifications of studies involving companion diagnostics and left-over samples, about 280 of them can be estimated to be made across the EU per year based on data provided by national competent authorities. Removing the notification requirement is expected to save around **€410,000** per year for sponsors and about **€112,000** in national competent authority resources.

Further savings can be expected from the gain in efficiency due to removal of these requirements, meaning that the studies can be started sooner and ultimately the devices may reach the market and patients faster.

Moreover, currently the number of such studies in the EU may be low due to the high administrative burden and therefore the sponsors' preference for conducting them elsewhere. The removal of the requirements is an incentive for more such studies to take place in the EU, stimulating innovation and ultimately faster access of EU patients to new devices.

Detailed analysis can be found in Annex IV - Table 3

3.2.2. Enable coordinated assessment for clinical performance studies and clinical investigations that are also part of clinical trials

Under the current framework, where a clinical investigation of a medical device is conducted jointly with a clinical trial of a medicinal product (for example, for a drug–device combination or a companion diagnostic), the sponsors must undergo two parallel regulatory processes—one under the MDR or IVDR for the device part and one under the Regulation (EU) No 536/2014 on clinical trials

on medicinal products (CTR)[28]. This dual process leads to a high administrative burden, difficulty for the sponsors to manage potentially different views of various Member State authorities, misaligned timelines and delays. The proposed revision is in line with the findings of the targeted evaluation on the need to increase the coherence between the MDR and IVDR with the CTR. The revision of the IVDR, MDR and CTR on this point enables a coordinated assessment between competent authorities responsible for the three Regulations, when both the device and the medicinal product are studied together. For the performance study or clinical investigation component that is part of a combined study, the sponsor has the option of going through a combined authorisation process described specifically for these studies in the CTR, rather than be subject to a separate assessment under either the IVDR or the MDR. This measure aims to reduce procedural fragmentation, facilitate integrated clinical studies, and align the EU framework with other major jurisdictions that already allow combined or harmonised submissions for such studies. It also responds to stakeholder feedback from industry on the need for more efficient processes for integrated studies involving both medical devices and medicinal products. Manufacturers are expected to benefit from reduced administrative workload and improved predictability, while national competent authorities would save resources by avoiding duplication of assessments and coordinating efforts across regulatory domains.

Cost savings:

Since the combined coordinated process would be put in place under the CTR, in this analysis focusing on the medical devices only a simple estimate of the reduction of administrative costs for the device part is made. In addition, since the great majority of combined studies involve IVDs rather than medical devices, the analysis is focusing on the cost savings for performance studies of IVDs that are linked to a clinical trial.

- Data from national authorities indicate an annual volume of 477 applications for performance study authorisations, of which approximately 78% are linked to clinical trials. Using an average of about 4-5 Member States per study, this gives about 80 studies linked to a clinical trial per year.
- For performance studies connected to clinical trials, administrative costs for sponsors and authorities amount to an estimated **€1.5 million per year**. Introducing a coordinated assessment is expected to reduce procedural duplication by around 30%, generating savings for the performance studies of approximately **€367,000 per year**.

These estimated savings do not take into account cost savings on the clinical trials side of the combined study or savings for clinical investigations of medical devices combined with a clinical trial. Moreover, they do not take into account missed opportunity costs due to delays to the start of the performance studies and clinical trials, which the stakeholders indicate as significant. The overall savings are therefore expected to be much higher than the above.

Detailed analysis can be found in Annex IV - Table 4

[28] *OJ L 158, 27.5.2014, pp. 1–76*, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

3.3. Summary of Safety and Clinical Performance (SSCP) and Summary of Safety and Performance (SSP)

The revision proposes a targeted streamlining of the SSCP under the MDR and the SSP under the IVDR, with the aim of reducing unnecessary documentation and validation burdens while preserving the transparency and accessibility of information.

Under the current framework, manufacturers of all implantable and Class III devices (MDR), as well as Class C and D IVDs (IVDR), are required to prepare a SSCP / SSP that is validated by the notified body and made publicly available for the users and, where relevant, for the patients. In practice, these summaries impose recurring costs for drafting, translation, validation and publication and, especially for IVDs, duplicate certain information already contained in the instructions for use (IFU), which are made available to users and will also be made publicly available through EUDAMED. Thus, the proposed changes are still in line with the general objective of the Regulations to ensure a high level of transparency of medical devices for all actors and citizens.

The proposed adjustments include the following:

- Remove the obligation to prepare an SSCP for class IIa implantable and WET devices, as well as for SSP for class C IVDs for professional use which are not companion diagnostics.
- Enable the manufacturer to draft the SS(C)P in a language readable by professionals and remove the requirement to provide an additional section in lay language.
- Remove the systematic requirement for notified body validation of the SS(C)P before publication. The SS(C)P would be reviewed as part of the technical documentation (TD) of a device either during initial certification or during surveillance (if the TD file is selected by the notified body).
- For IVDs, remove overlapping content with the IFU to ensure that the SSP provides easy-to-navigate non-duplicative information, and make the IFU publicly available through the EUDAMED database.

These measures maintain transparency while avoiding duplication and non-essential costs for higher-risk devices while reducing burden for lower-risk devices. Manufacturers would benefit from reduced drafting, translation, and validation costs, and notified bodies would save resources by reviewing less documentation. At the same time, clinicians, patients and researchers would continue to have access to the additional information from the SS(C)P on clinical and performance evaluation on the higher-risk devices.

Cost savings:

Cost saving is expected for internal manufacturer costs due to the removal of validation costs by the notified body and the reduction of the number of pages in the SS(C)P files, and.

- The notified body fees for initial validation of SS(C)Ps vary between €1 200 – 4 000 per document. The savings expected from removing this separate validation step are around **€20.7 million**. In addition, assuming that there is one update per year of the SSCP document, which would currently also need to be validated by the notified body with similar fees, there would be additional savings on the order of **€20 million** per year.

- The manufacturer costs for drafting and translating an SSCP reach €42 000 – 70 000, with the equivalent costs for an IVD SSP of €17 250 – 28 750. Removing the part of the SSCP in lay language, for those SSCPs that are likely to have this additional part, can generate savings of around €**13 million**. For IVDs, there is an additional cost saving from removal of duplication with the instructions for use. The combined reduction of the number pages of the SSP for IVDs is expected to yield a saving of **€11.3 million**.

Detailed analysis can be found in Annex IV - Table 5

PART II – ELEMENTS OF CONFORMITY ASSESSMENT

Proposed measures – Part IIA

3.4. Simplification and clarification of classification rules

The revision proposes a targeted revision and clarification of the classification rules under Annex VIII of the MDR, with the objective of improving legal clarity, predictability, and consistency in the application of classification principles. This adjustment does not alter the overall level of safety and performance required for medical devices; rather, it ensures that products are classified in a consistent and proportionate manner across the Union, to ensure smooth functioning of the internal market, and improve the competitiveness of the Union.

The key proposed changes include:

- Re-classification of reusable surgical instruments intended for transient or short-term use to class I, under Rules 6 and 7, recognising their long history of safe use and standardised manufacturing.
- Re-classification of most accessories for active implantable devices, meaning that they would be classified in their own right based on actual risk, instead of being automatically assigned to the highest class (Rule 8).
- Re-classification of well-established technologies (WET) used as components in joint replacements or spinal disc replacements, reflecting mature designs and extensive post-market data (Rule 8).
- Addition of accessories for Annex XVI products (i.e. products with no medical purpose but similar function or risk profile) and adaptation of Rule 9 to cover these products, ensuring coherent treatment under the MDR.
- Alignment of software classification (Rule 11) with international guidance (e.g. IMDRF/SaMD WG/N81 FINAL: 2025), leading to re-classification of certain software

functions whose risk lies primarily in information provision rather than direct patient management.

These proposed changes strengthen legal certainty for manufacturers and authorities by codifying long-standing interpretations and aligning classification approaches with international norms. They aim to reduce divergent national or notified body interpretations, which currently lead to inconsistent classification outcomes for similar products.

By ensuring that classification reflects actual risk and technological maturity, the revision enhances predictability and proportionality within conformity assessment procedures. This contributes to greater transparency of regulatory pathways, which is particularly beneficial for SMEs and software developers entering the EU market. Importantly, the simplifications do not affect patient safety, as the above proposed classification is appropriate for the risk posed by the devices, and they would still undergo conformity assessment according to the procedures determined by that class, as well as being subject to post-market surveillance, market surveillance and vigilance requirements.

Collectively, the proposed adjustments clarify the boundaries between classes, reduce interpretative divergences among manufacturers, notified bodies, and competent authorities, and provide clearer guidance to manufacturers at the earliest stages of product development.

The cost savings from this measure arise both from avoiding disproportionately rigorous and costly conformity-assessment procedures for the devices concerned, and from consequently enabling their faster access to the market. It also promotes a more efficient use of notified body resources, allowing them to focus on higher-risk or more complex assessments where their expertise is most needed. Greater regulatory efficiency resulting from this measure would also help ensure that patients benefit from an earlier and broader availability of these devices.

Note: While this measure is expected to generate efficiencies and potential cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.5. Simplifying Processes – Maintenance of certificates

3.5.1. Change management

The medical device and *in vitro* diagnostic medical device sectors are characterised by continuous iterative technological improvements. Manufacturers routinely introduce design refinements, process optimisations, or material substitutions to enhance device quality or adapt to evolving standards. This implies changes to their quality management system (QMS) or technical documentation of devices, which may be covered by QMS or product certificates.

There are different levels of oversight for changes, depending on their extent. Certain changes can be implemented by the manufacturer without the need for prior approval of the notified body, with some of these needing to be reported. Major changes need to be assessed by the notified body, who would decide whether additional conformity assessment activities and / or updates of the certificate(s) are needed.

To support a more proportionate and internationally aligned approach for changes that currently require prior approval from a notified body, the revision would introduce the possibility of a predetermined change control plan (PCCP). This plan would be agreed between the manufacturer and the notified body in advance, defining the boundaries within which modifications may be implemented without further prior notified body notification and approval. The type of change that

could be covered by it can include certain changes related to the manufacturing process (e.g. replacement of equipment) or to the characteristics of the product (e.g. changes to the shelf life of the device when there is a validated protocol for its determination, or certain changes to software as a medical device). This approach is aligned with international regulatory principles, in particular with the work of the IMDRF on change management of software, promoting global convergence and predictability for manufacturers operating in multiple jurisdictions. It aims to provide a structured and transparent mechanism for handling changes, improve predictability and efficiency to the change management process while maintaining a high level of regulatory oversight through a continued control over modifications that could impact safety or performance. Manufacturers are expected to benefit from reduced administrative and compliance costs and shorter timelines linked to change notifications. Notified bodies would save resources by preliminary approval of planned changes and decrease of change notifications thereof. Patients would benefit from timely access to improved devices, as non-critical changes can be implemented more rapidly without compromising safety or performance.

Cost savings:

- An estimation of number of changes submitted to notified bodies per year was estimated based on surveys with both notified bodies and manufacturers, for QMS distributed according to manufacturer size and for technical documentation independent of manufacturer size. Average notified body review fees amount to around €17,500 per QMS change and €52,500 per technical documentation change.
- Estimates from industry indicate that savings from managing eligible changes under a PCCP would be about a third of current costs. This factor considers that firstly only certain changes would be eligible to be covered by a PCCP, and secondly that preparing and reviewing the PCCP would also generate certain costs.
- Combining the above information for both medical devices and IVDs, the shift of eligible changes into PCCPs would generate annual savings of approximately **€477.6 million**.
  This calculation does not take into account the internal administrative costs of the manufacturers, which would also decrease if eligible changes can be managed under a PCCP rather than individually. Therefore, the above saving is likely to be an underestimate.

Detailed analysis can be found in Annex IV - Table 6

3.5.2. Surveillance frequency

The proposed revision provides for a more flexible approach to the frequency of surveillance audits performed by notified bodies as part of the conformity assessment activities under the Regulations. Currently, manufacturers are subject to annual surveillance audits irrespective of their portfolio, the nature of their devices, the performance of their QMS, or post-market feedback. While this aimed at ensuring continuous oversight, a high frequency of surveillance audits for all manufacturers may not always be proportionate to the level of risk or justified by available post-market data.

With a more proportionate approach aimed at improving efficiency, the revised framework would allow surveillance audits to take place every two years, where this is supported by good compliance history of the manufacturer and absence of concerns coming from post-market feedback.

Manufacturers are expected to benefit from lower audit-related costs and reduced operational disruption, while notified bodies would save time and resources by focusing surveillance efforts on manufacturers or devices that present higher or evolving risks.

Cost savings:

- Annual surveillance audit costs for MDR and IVDR manufactures are around €13,750 for micro and small manufacturers, €37,000 for medium-size manufacturers, and €85,000 for large manufacturers.
- These costs can be applied to the expected future number of MDR and IVDR certificates distributed by enterprise size (8,452 micro/small; 3,694 medium; 3,229 large) and reduced by 20% to take account of activities that may be combined (e.g. with MDSAP or ISO 13485). This yields a total annual surveillance audit burden of approximately €529 million.
- Allowing surveillance audits to take place **every two years, where justified** based on compliance history, PMS/vigilance performance, and the absence of significant safety concerns, would reduce the number of audits required each year. It can be reasonably assumed that between 10-50% certificates could benefit from biennial rather than annual audits.
- Taking a 30% eligibility rate for reduced-frequency audits, annual savings can be estimated at: **€63.5 million**.

This calculation does not take into account the reduction in internal costs of the manufacturer and less disruption to the operation of the manufacturer due to lower audit frequency, so this is expected to be an underestimate.

Detailed analysis can be found in Annex IV - Table 7

3.5.3. Sampling of technical documentation

Under the current Regulations, notified bodies are required to assess the TD for "at least one" representative device per generic device group (class IIb and C) and per category (class IIa and B) prior to issuing a certificate. In addition, notified bodies must continue assessing technical documentation on a sampling basis during surveillance activities, ensuring that the entire range of devices covered by the certificate is sampled during the certification period. In practice, this formulation in conjunction with the MDCG guidance on sampling has resulted in high time and resource costs for both manufacturers and notified bodies, and divergent practices hampering the functioning of the internal market. While this systematic approach provides continuous verification, it is unwarranted for devices with proven safety and performance history supported by post-market data. It may even include repetitive review of unchanged documentation.

To strengthen proportionality and efficiency, the proposed revised approach is to:

- require that only one TD per representative generic device group or category is assessed for initial certification for classes IIa and IIb medical devices and class C IVDs, and one device per manufacturer's portfolio for class B IVDs;
- exclude assessment of aspects related to the design for class IIa devices;
- apply a more proportionate approach during initial certification of devices that are well established technologies;
- discontinue the requirement for systematic annual TD sampling during surveillance audits;

- limit TD reviews after initial certification to "for cause" assessments, triggered by specific information from vigilance, PMS a, significant changes notified under the QMS, possible QMS non-compliances, or other justified concerns; and
- clarify that notified bodies remain empowered to request TD review at any time where necessary to verify continued compliance.

These measures shift the approach from regular comprehensive activities to more risk-based selective oversight, reducing burden and ensuring that regulatory attention is focused on areas where it adds demonstrable value to patient safety. Manufacturers would see reduced administrative costs related to TD sampling, while notified bodies would be able to use their time and expertise more efficiently by limiting detailed reviews to cases where the level of risk warrants it, such as cases where PMS, vigilance trends, QMS findings or significant changes may indicate a genuine safety or performance concern.

Cost savings:

- TD sampling under the current regime represents a major recurring cost driver. The biggest one is the sampling during annual surveillance after the certificate is issued, so the cost saving calculation is focusing on this element.
- The number of generic device groups / categories per manufacturer, the typical number of TDs reviewed per surveillance, and sampling fees can vary. A representative TD sampling landscape for different manufacturer sizes and device classes was developed using data from notified bodies, analysis of certificates and expert input.
- The total current costs of TD review on a sampling basis during annual surveillance were estimated at **€1.4 billion** per year**.**
- Removing systematic TD sampling and limiting reviews to "for-cause" assessments would substantially reduce annual review volumes. Three scenarios were modelled, with "for-cause" assessments accounting for 10%, 20% or 30% of current TD review volume. Using the 20% rate, the annual savings amount to **€1.1 billion.**

These savings calculations are based only on the notified body review fees and do not take into account the decrease in manufacturer internal administrative costs associated with the lower TD sampling rates. The real savings should therefore be even greater.

Detailed analysis can be found in Annex IV - Table 8

3.5.4. Unannounced audits

Under the current provisions of the Regulations, notified bodies must perform at least one unannounced audit during each five-year certification cycle. This strict requirement ensures a high level of regulatory control but applies flatly to all manufacturers, without considering real needs, track record of compliance, or the manufacturer's performance in PMS, ultimately resulting in possible superfluous verifications being conducted. The revision introduces a more targeted and risk-based approach to unannounced audits conducted by notified bodies.

The revised approach replaces the mandatory frequency with a more flexible needs-based principle, whereby unannounced or short-notice audits are carried out "for cause", e.g. based on vigilance cases, non-compliance, PMS outcomes, or market surveillance signals. Routine unannounced audits would therefore no longer be a fixed procedure applied uniformly to all manufacturers but would remain a valuable tool for notified bodies to be applied in case of potential risk or concern.

This change maintains the high level of safety required under the Regulations while aligning audit practices with the principles of proportionality and evidence-driven oversight. It would also reduce unnecessary burden and generate cost savings for manufacturers, while freeing up notified bodies' resources to focus on areas of higher regulatory relevance.

Cost savings:

- Under the existing fixed requirement of one unannounced audit per five-year cycle, across all MDR and IVDR expected QMS certificate holders, unannounced audits currently entail an estimated total cost of **€200 million.**
- By replacing the fixed frequency with a targeted, risk-based approach, the number of audits would decrease. Three scenarios were considered, in which 30%, 50% or 70% of audits would remain. The 50% reduction would result in total estimated savings of **€62.7 million per year.**

This calculation does not take into account the internal manufacturer costs related to audit activities as well as the savings from the manufacturer's operational disruption during the audit. Therefore, the actual savings are expected to be greater.

Detailed analysis can be found in Annex IV - Table 9

3.5.5. Replacement of 're-certification' by periodic review and removal of general duration limit of certificates

The revision replaces the current re-certification process with a system of periodic review of certificates conducted by notified bodies. Under the existing framework, certificates are limited to a maximum duration of five years, at the end of which a re-certification procedure is required. According to some stakeholders, this in practice creates unnecessary duplication of work already performed, significant administrative burden with limited added value in terms of safety benefit and possible negative impact on tender procedures and third-country registrations. The heavy re-certification procedure also presents unnecessary overlap with continuous post-market surveillance of the manufacturer, the surveillance by the notified bodies, and market surveillance and vigilance.

The measure introduces a more proportionate regular review mechanism in the form of periodic review of certificates, ensuring continuous oversight of certified devices while reducing administrative burden and possible duplication of assessments. Periodic review would focus on elements relevant to guarantee continued compliance such as alignment to the state of the art, impact of changes, and PMS outcomes. The revision also proposes removal of the maximum five-year validity limit for certificates issued by notified bodies and a system in which certificates remain valid provided that the manufacturer continues to comply with the applicable requirements as confirmed by the notified body's oversight. Notified bodies would nevertheless retain the possibility to limit certificate duration when needed.

This measure is expected to generate cost savings for manufacturers and reduce the administrative burden associated with full-recertification cycles. It would also save time and resources for notified bodies. Removing the maximum validity aims to reduce administrative workload for both notified bodies and manufacturers, ensuring uninterrupted market presence of compliant devices and avoiding administrative bottlenecks. The measures are also expected to facilitate third-country regulatory registrations, as many jurisdictions require proof of valid up-to-date EU certifications. All in all, it

reflects a shift from fixed validity cycles to continuous monitoring based on performance, risk and post-market data.

Cost savings:

- Re-certification for the quality management system currently involves an audit, with a major factor in the cost being the size of the manufacturer and their portfolio (e.g. **€20,000** for a micro manufacturer and **€100,000** for a very large manufacturer). It also involves sampling of the technical documentation, similar to what would be expected in a typical surveillance year. For technical documentation certificates, the re-certification involves review of the technical documentation taking into account possible changes that might have been made during the certification cycle.
- Cost reductions from the proposed measure include:
  - around 10% administrative savings from removing the need for re-issuance of the certificate,
  - the reduction of technical documentation sampling activities during surveillance, taking into account the policy change described in section 3.5.3, applying a somewhat lower saving due to some additional activities of scanning and reviewing changes in technical documentation,
  - for product certificates the reduction of costs of technical documentation review due to the expected reduced depth of assessment to about 60%.
- Combined savings across medical device and IVD sectors from the above factors can reach an aggregate of €1.1 billion per current 5-year cycle, or about **€227 million** per year.

This calculation does not take into account the reduction in internal manufacturer costs due to lighter periodic review activities, as well as lower administrative costs associated with liaison with third-country authorities where the device may also be registered, in order to inform them of the change. The saving calculated above is therefore likely to be an underestimate.

Detailed analysis can be found in Annex IV - Table 10

3.5.6. Periodic Safety Update Reports (PSURs)

Under the current framework, manufacturers of class IIa, IIb and III MDs and class C and D IVDs must prepare PSURs at fixed intervals and, for higher-risk devices, submit them to notified bodies for validation. The revision streamlines the PSUR requirements, introducing a more proportionate approach to reporting and review, based on device class, risk, and post-market experience.

The targeted evaluation identified a need to streamline reporting requirements in the context of post-market surveillance.

To improve proportionality while maintaining the same level of safety oversight, the proposal for revision is to:

- exclude custom-made devices from the PSUR requirement, recognising their individualised nature and low public health impact;
- remove the requirement for regular notified body evaluation of PSURs;
- reduce the fixed frequency of PSUR updates for class IIb and III devices and class C and D IVDs to every two years, instead of annually;

- allow class IIa implantable device manufacturers to update PSURs only when necessary, based on post-market data or identified trends.

At the same time, notified bodies and competent authorities may continue to request PSURs or conduct targeted reviews were justified by vigilance data or market surveillance findings.

This approach preserves the integrity of post-market safety monitoring while reducing duplication and administrative burden. By limiting reporting to what is necessary and proportionate, manufacturers are expected to benefit from significant cost savings and reduced administrative workload. At the same time, the removal of routine notified body validation for certain device categories would free up notified body resources, enabling them to focus on higher-risk areas and improving overall system efficiency.

Cost savings:

- Based on extrapolation of data provided by notified bodies, around 15,700 medical device and 2,000 IVD PSURs can be expected after the transition to the Regulations is completed. Updating these PSURs on a yearly basis currently entails around €78,5 million for medical devices and €8,0 million for IVDs in notified body fees. Updating these PSURs on a yearly basis currently entails manufacturer internal costs of around €78,5 million for medical devices and €8,0 million for IVDs.
- Under the revised framework, removing the requirement for annual update for class IIa implantable devices and reducing the frequency of mandatory update from one to two years for the remaining devices would result in aggregate savings of about **€53.7 million annually**.
- The proposed measure also includes the requirement to update the PSUR when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. This is not taken into account in the cost savings calculation as this type of update is already expected to take place today and would not change under the proposed revision.

The calculation does not take into account the cost savings from the reduction in the frequency of notified body evaluations, both due to the reduced frequency of update of PSURs by the manufacturer and possible reduced frequency of annual surveillance activities described in section 3.5.2.

Detailed analysis can be found in Annex IV - Table 11

3.5.7. Analysis of serious incidents

The proposal for revision refines the vigilance process by clarifying the respective roles of competent authorities and notified bodies in the evaluation of serious incidents and field safety corrective actions under Articles 87 and 89 MDR and Articles 82 and 86 of the IVDR. Under current practice, notified bodies are often involved in incident assessments alongside competent authorities, which can lead to duplication of assessment, high costs and extended handling times.

The proposal envisages to remove the systematic requirement for notified body participation and require their review only for serious incidents linked to a field safety corrective action, a serious public health threat or where assistance is requested by the competent authorities.

These measures aim to streamline vigilance processes by reducing parallel evaluations and redundant correspondence between manufacturers, notified bodies, and national competent authorities. Notified bodies would only assess the most critical cases, reducing duplication with the work of the competent authorities. The authorities would still retain the possibility to request their assistance when needed. Therefore, this measure can be considered to keep the same level of patient safety, since all serious incidents would still be reviewed by the competent authorities and notified bodies would be involved in a proportionate manner. However, manufacturers would have less administrative burden and less cost to bear, since fewer formal submissions to notified bodies would be required. Moreover, notified bodies would save significant time and resources from reviewing fewer submissions.

Cost savings:

- Based on data from national competent authorities about 144,000 serious incidents are reported per year across the Union market for medical devices and about 5,000 for IVDs.
- The current handling cost of a serious incident report by notified bodies is around €400 per report.
- Removing the systematic requirements for notified body assessment would result in estimated annual cost savings of **€50 million** across medical devices and IVDs.

The costs of notified body handling of serious incidents related to field safety corrective actions and serious public health threats are significantly higher. However, these activities are expected to continue, therefore their cost is not taken into account in this calculation.

Detailed analysis can be found in Annex IV - Table 12

Proposed measures – Part IIB

3.6. Simplification measures specific to certain devices

3.6.1. Well-Established Technologies (WET)

The revision introduces a definition of WET to ensure a proportionate application of regulatory requirements for devices with a proven record of safety and performance. Rather than relying on static lists, such as the one in Article 52(4), the concept would be based on criteria codified in a definition in Article 2. To maintain a high level of legal certainty, the Commission would retain the empowerment to draw up a non-exhaustive list of devices that should be considered to meet, or to not meet, the criteria of the new definition of WET devices.

In the proposed revision, a device would qualify as a WET if it meets the following criteria: it belongs to a generic device group with a simple, common and stable design, the generic device group is not associated with safety issues in the past, has well-known clinical performance characteristics and a long history on the Union market, and the device is a standard of care device with little evolution in indications and the state of the art. These strict criteria have been defined in line with the objectives of the Regulations to ensure a high level of protection of health for patients and users.

Consequently, WET devices would benefit from targeted regulatory flexibilities, including:

- Exemption from implant-card obligations under Article 18 MDR;
- Simplified conformity assessment procedures under Article 52 MDR;
- Adapted clinical evidence requirements under Article 61 MDR.

The aim of these measures is to reduce unwarranted compliance burden for these devices, increase flexibility by introducing an adaptable, criteria-driven approach and have the option to further increase legal certainty via the empowerment for non-exhaustive lists of such devices. This set of measures would help focus regulatory oversight on higher-risk or novel technologies. By virtue of lightening the evidence generation and documentation obligations for WET devices, manufacturers would experience notable cost savings and decreased administrative burden. At the same time, the streamlined treatment of WET would allow notified bodies to reallocate capacity towards higher-risk or innovative technologies, resulting in significant time savings and more efficient use of expert resources. Patients would ultimately benefit from lower costs and potentially greater variety of these devices available on the market as a consequence of lower regulatory hurdles for them.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.6.2. Class I reusable medical device surgical instruments and class A sterile IVDs

Under the current framework, notified bodies are involved for class I reusable surgical instruments (also referred to as class Ir devices) to assess aspects related to the cleaning, disinfection, sterilisation, maintenance, and functional testing. As for class A sterile IVDs, the notified body involvement focuses on aspects related to sterility.

To improve proportionality of the regulatory framework, the proposal envisages that where manufacturers of class I reusable surgical instruments have applied harmonised standards or common specifications covering all relevant aspects of these requirements, the involvement of a notified body would no longer be necessary. The simplification is conditional on the availability of the harmonised standards or common specifications. Given that this is a relatively large group of products, it is likely that there would be significant interest in developing the standards or common specifications and that they would become available in a few years. The proposed simplification is therefore very likely to be applied in practice.

For class A sterile IVDs, the intervention of a notified body is proposed to no longer be required, while the same safety and performance requirements would still apply to the manufacturer. IVD sterility can be very important for generating correct results, however it is an established practice where standards are available. The risk is also not comparable to class I sterile medical devices which come into direct contact with the patient. Therefore, self-declaration by the manufacturer, a practice which was already in place under Directive 98/79/EC, can be considered appropriate for class A sterile IVDs, in addition to vigilance and market surveillance generally applicable to all devices.

For both class I reusable surgical instruments and class A sterile IVDs, the proposal reflects the extensive standardisation and long-standing safe use of such instruments across healthcare settings and better aligns the level of regulatory oversight with the level of risk of these devices. It would reduce administrative burden and remove notified body fees for manufacturers, generating tangible cost savings for them, especially for SMEs as they tend to be more active in devices of lower risk classes. It would also free up notified body resources to focus on higher-risk devices. Similarly to WET devices, patients would benefit from lower costs and potentially greater variety of these devices available on the market as a consequence of lower regulatory burden for them.

Cost savings:

- The number of QMS certificates expected to cover class Ir devices after the transition to the Regulations is completed can be estimated to be about 700, and those covering class A sterile IVDs at about 24. Notified body fees for certification for these devices can be estimated at around €32,000.
- These fees would no longer be applicable in case of no notified body involvement, for class Ir where harmonised standards or common specifications are applied. The resulting savings amount to approximately **€22.5 million** for class Ir devices and **€767,000** for class A sterile devices**.** Combined across both categories, the total average saving is **€23.3 million**.

Detailed analysis can be found in Annex IV - Table 13

3.6.3. Technical documentation of near-patient tests

The proposal for revision aims to simplify technical documentation assessment for near-patient tests. Near-patient tests are a small but important category of IVDs. They are performed by professional users but unlike other professional-use tests for which the patient specimen is sent to a laboratory, the near-patient tests can be done next to the patient or in the clinic where the patient is being examined. Examples include rapid antigen infectious agent tests, C-reactive protein tests, blood coagulometers or urinalysis dipsticks. Currently, they are subject to individual technical documentation assessment regardless of the class they fall in. However, many near-patient test technologies have now been in use for decades and benefit from mature, standardised and increasingly automated technologies, and are operated by trained healthcare professionals within controlled clinical environments.

For the professional use tests the primary determinant of risk can be considered to be the clinical impact of an incorrect result and the device's inherent characteristics, rather than where the test is performed. Therefore, the revision proposes to treat them similar to other professional use devices of the same class as regards assessment of technical documentation. This means that near-patient tests falling in classes B and C would be subject to technical documentation assessment on a sampling basis. For class B near-patient tests only one device out of the manufacturer's portfolio, and for class C near-patient tests one device out of a category of devices would be assessed by the notified body during initial certification.

Cost savings:

- According to industry estimates of the number of near-patient tests on the EU market is around 1500[29]. The majority of them is likely to have not yet transitioned to the IVDR as the transition deadlines for class C and B devices are in 2026 and 2027 respectively.
- Using typical notified body fees for technical documentation assessment, the cost saving for these devices moving from a comprehensive to a sampling-based approach would be around **€68 million.**

[29] MedTech Europe, *Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies*, September 2021.

- In addition to this one-off cost, assuming that around 5% new near-patient tests would be coming on the market, a yearly saving of **€3.4 million** can be expected only from the simplification related to the initial certification.

This does not take into account additional savings expected from the internal costs of the manufacturer related to the notified body's assessment. It also does not take into account further savings expected from reduction in annual surveillance of the technical documentation certificates. Therefore, the above saving is likely to be an underestimate.

Healthcare is becoming increasingly decentralised and personalised, and technology development enables more portability and faster results with similar performance to laboratory-based tests. As the availability and use of near-patient tests grow, the associated cost savings generated by a more proportionate regulatory approach would also increase, amplifying the overall benefit for health systems.

Detailed analysis can be found in Annex IV - Table 14

3.6.4. In-house devices

The revision introduces targeted flexibilities for devices manufactured and used within health institutions under Article 5(5) of the Regulations (so-called in-house devices).

Under the current framework, health institutions must meet certain documentation and justification requirements. Health institutions have reported that these new obligations are burdensome, particularly for public hospitals and diagnostic laboratories operating under accredited quality systems, often leading to repetitive paperwork and shifting staff time from clinical or diagnostic activities. Moreover, the high burden and notably the need to justify that that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market discourages health institutions from investing into the development of in-house devices with adverse effects both for the needs of patients and for the preparedness for crises and emergency situations (such as during the COVID-19 pandemic).

To improve proportionality and reflect the special nature of in-house device manufacturing, the proposal introduces the following simplifications:

- transferability: allow the transfer of in-house devices between health institutions, provided that there is duly justified interest of public health or patient safety or health;
- justification for absence of equivalent CE-marked devices: introduce a 10-year transition period for health institutions to adopt a suitable equivalent CE-marked device once such a product becomes available for medical devices, and remove this condition for IVDs, for which it is considered particularly burdensome;
- accredited laboratories (IVDR): where a health institution is accredited under ISO 15189, the requirement to draw up full documentation demonstrating compliance with Annex I (general safety and performance requirements) is proposed to be waived, recognising that accreditation already ensures a comparable level of quality control and traceability.

These simplifications would benefit health institutions by reducing the costs and time required for compliance and allowing them to invest resources into treating patients rather than administrative tasks. They would also benefit patients, in particular those suffering from rare conditions for which commercial devices are not available, as health institutions would be better able to satisfy their needs.

Cost savings:

- Setting up and maintaining an Article 5(5) compliant system typically requires substantial investment by health institutions, including a significant time investment and initial system-establishment costs of approximately **€176,000 for medical devices** and **€200,000 for IVDs**, and recurring annual maintenance and staff needs amounting to **€42,000 for medical devices** and **€34,000 for IVD**. In case of possibility to transfer the in-house device for use in another health institution, the receiving health institution would not have to incur these costs.
- The 10-year transition period, or removal of the justification condition, allows health institutions to continue using in-house devices when an equivalent CE-marked alternative becomes available, avoiding immediate replacement.
    - This means that the above costs incurred by the health institution for the development of the manufacturing system, plus additional costs to create the documentation of the in-house device, would not be rendered obsolete.
    - The extended transition period or removal of the condition would also provide more time for market competition to drive down prices and improve performance of the alternative CE-marked devices. Health institutions report that CE-marked devices currently replacing in-house devices can be about 5 times more expensive, and they can have higher running costs, which the health institution is currently obliged to bear. Moreover, their performance may not be superior to the in-house device, making the costs of changeover difficult to justify. With a longer transition time, these negative consequences of an obligatory immediate switch to the first available CE-marked device can be mitigated.
    - Thirdly, the proposal would preserve the incentive for health institutions to develop in-house devices, therefore better addressing the needs of patients and developing expertise and infrastructure essential for crisis response.
- For IVDs, accredited laboratories operating under ISO 15189 would benefit from an exemption from the device documentation, avoiding substantial documentation and justification requirements. Health institutions report that preparing the technical documentation in addition to what is already required by ISO 15189 can range from **5 to 1,000 pages** and demand between **8 and 2,880 hours**, with the corresponding cost ranging from **€400 to €140,000**. This illustrates the significant administrative burden that could be avoided for these accredited institutions under the revised framework.
- The number of in-house devices and health institutions across the EU is difficult to estimate as there is no universal requirement to notify them. Member State policy towards in-house devices can also vary, so they can be more widespread in some Member States compared to others. Belgium has a publicly available portal where health institutions need to register themselves and their devices and currently has 43 registered health institutions and a total of around 1600 in-house devices. However, some institutions have not registered any devices yet, so this number is likely to be an underestimate. A study of one university hospital shows that one health institution can have as many as 500 in-house devices (*Vermeersch P, Van Aelst T, Dequeker EMC. The new IVD Regulation 2017/746: a case study at a large university hospital laboratory in Belgium demonstrates the need for clarification on the degrees of freedom laboratories have to use lab-developed tests to improve patient care. Clin Chem Lab Med. 2020 Jul 21;59(1):101-106. doi: 10.1515/cclm-2020-0804. PMID: 32692695*). This is likely to be an overestimate compared to the EU-wide average as this is a large health institution. All in all, the number of in-house devices across the EU is likely to be in the tens to hundreds of thousands, used in several thousands of health institutions. The savings from the above simplifications are therefore likely to be significant.

3.6.5. Orphan and Breakthrough Devices

The proposal for revision introduces a dedicated regulatory pathway for orphan and breakthrough medical devices and IVDs. Under the current framework, there are no specific provisions to facilitate the assessment or market entry of devices addressing rare conditions or introducing high levels of technological or clinical innovation. This has led to fragmented treatment of such devices and longer time-to-market compared to jurisdictions with dedicated programmes, delaying patient access to technologies with potentially transformative impact on health outcomes and healthcare systems.

Breakthrough and orphan devices often originate from start-ups, SMEs, and academic innovators, which face significant challenges in generating extensive pre-market evidence despite the potential of their technologies to deliver substantial clinical or public-health benefits. Many of these devices target unmet medical needs, including rare diseases or life-threatening conditions with limited or no existing alternatives, where small patient populations make evidence generation costly and complex, amplifying the burden on manufacturers with low sales volumes.

The proposed new framework establishes eligibility criteria for designation as a breakthrough or orphan device, supported by an expert panel opinion. Through the empowerment for an implementing act, it aims to further introduce prioritised and rolling review during conformity assessment and allow for conditional certification where benefits of early access outweigh residual uncertainty, provided that additional clinical data are collected post-market. This approach reduces the regulatory burden and associated costs for developers while enabling earlier access to promising technologies for patients with urgent or rare conditions. Thus, the proposed framework would contribute to the general objective of the Regulations to ensure a high level of protection of health for patients and users. This measure aligns the EU framework with international best practices and provides a more predictable route for innovative developers while safeguarding patient safety, ultimately accelerating access to breakthrough innovation and supporting healthcare systems in addressing unmet medical needs more efficiently.

Cost savings:

The numbers of both orphan and breakthrough devices are likely to be small, due to their special nature, but the cost savings a manufacturer of either device type can be significant. The main benefit from the policy would be for patients who would gain faster access to these devices which could be essential for them. It is particularly difficult to estimate the number of orphan devices, to quantify savings during conformity assessment for both types of devices and to quantify the impact on patients. The below cost savings analysis focuses on quantifying opportunity-cost savings for breakthrough devices due to expected shorter time-to-market.

- Prioritised assessment of breakthrough devices could shorten certification timelines by at least 3 months, accelerating access to market. Considering different scenarios of device complexity, price and volumes sold, estimated average opportunity-cost savings from the earlier market access possibility are at €1,500-4,500 per device.
- Assuming that 80 breakthrough devices are certified out of an estimated 165 designated per year (based on data from comparable market data from US FDA), this could result in estimated cost savings of around **€570 million per year**.

This calculation considers only one aspect of savings from the described measures, as explained above. Therefore, this amount is an underestimate.

Detailed analysis can be found in Annex IV - Table 15

3.6.6. Grandfathering of Orphan Medical Devices and IVDs Already on the Market

The proposal for revision introduces a derogation mechanism allowing certain legacy devices that qualify as orphan devices to remain on the market beyond the current transitional deadlines. This measure addresses situations where withdrawal of such devices could leave patients with rare diseases without suitable alternatives, as the costs of compliance are too high for the manufacturers of such devices. The proposal would therefore help ensure continued access to essential technologies while avoiding unnecessary regulatory and financial burdens for manufacturers.

According to the proposal, devices that meet the orphan device criteria, as confirmed by an expert panel, may continue to be placed on the market or put into service, provided that they:

- continue to comply with the essential requirements of the Directives[30];
- have not undergone significant changes in design or intended purpose; and
- do not present any unacceptable risk to patients, users, or public health.

These devices would not bear the CE marking but must include a clear statement in the EU declaration of conformity and associated documentation indicating that they are placed on the market under this specific derogation. Manufacturers remain subject to the Regulations' provisions on post-market surveillance and vigilance, including annual PSUR submission and, where required, post-market clinical follow-up. The post-market oversight of these devices is proposed to be ensured by the national competent authorities. This measure would significantly reduce manufacturers' compliance costs, save notified bodies' resources that would otherwise be spent reassessing long-established low-volume orphan devices, while safeguarding patients' continued access to essential treatments and avoiding unnecessary shortages. National authorities would need to carry out additional post-market monitoring activities for these devices; however, this workload remains significantly lower than the full conformity assessment that would otherwise be required from a notified body. Given that the number of such devices is expected to remain limited, the additional effort for national authorities is likely to be outweighed by the benefits described above, most importantly the continued availability of these devices for patients.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

[30] Council Directive 93/42/EEC (MDD) on medical devices, Council Directive 90/385/EEC on active implantable medical device and Directive 98/79/EC on in vitro diagnostic medical devices.

3.6.7. Fee reductions

The proposal for revision introduces fee reductions to ensure a more proportionate and equitable cost structure, particularly for smaller economic operators and for manufacturers of orphan devices. Under this new proposed provision, notified bodies would be required to apply at least a 50% fee reduction for micro-enterprises and at least 25% fee reduction for small enterprises, as well as at least 50% reduction for conformity assessment of orphan devices. This measure promotes a level playing field for micro and small companies, supports early-stage innovators, and ensures that cost considerations do not hinder the development or maintenance of devices addressing rare diseases. Overall, these measures would ease the financial burden on micro and small companies, while also sustaining continued availability of devices serving very small patient populations and supporting overall system resilience.

Cost savings:

This calculation is focusing on the fee reductions for micro and small enterprises. The fee reductions for orphan devices would make a further contribution, however it is challenging to estimate due to lack of quantitative data on the number of orphan devices. The number of applications from manufacturers of orphan devices per year is expected to be small.

- Across MDR and IVDR, notified bodies can be expected to receive approximately 834 applications per year from micro-enterprises and 1,428 from small enterprises, considering both applications for new certificates and for changes to existing certificates.
- Under the revised provisions, notified bodies must apply at least a 50% fee reduction for micro-enterprises and 25% for small enterprises. Application of these factors to the annual application volumes in both medical devices and IVD, taking into account different costs of conformity assessment for different risk classes, results in a total estimated saving for these manufacturers of **€90 million** per year.

Detailed analysis can be found in Annex IV - Table 16

3.6.8. Companion diagnostic (CDx) consultation

Currently the IVDR requires a consultation of the medicinal products authority (in practice most frequently the European Medicines Agency (EMA)) on the suitability of the companion diagnostic in relation to the medicinal product. The proposal simplifies the scope of the consultation by limiting it to the suitability of clinical performance only. It also clarifies that this consultation should not duplicate the assessment of the notified body, which would fully assess all aspects of the device in accordance with the IVDR. Moreover, devices that have the same intended purpose and performance as another device that already underwent the consultation are proposed to be exempt from the consultation requirement.

Cost savings:

- The current consultation cost of the EMA is **€56,500**, with an additional **€5,000** charged for assessment of changes to the device. The proposed simplifications should result in both the reduction of the fee per consultation and the frequency of the consultation. Moreover, there would also be significant savings of costs internal to the manufacturer and to the

notified body linked to the interaction with the medicinal product authority, as well as resource savings at the EMA and the national competent authorities for medicinal products.

3.6.9. CDx – association of similar medicinal products

Currently, the IVDR requires that the International Nonproprietary Name(s) (INNs) of the associated medicinal product must be indicated in the intended purpose of the device and associated documentation of a CDx IVD. Adding a new medicinal product to the intended purpose of a CDx is currently considered by the notified bodies as requiring a new conformity assessment, regardless of whether the new medicinal product is similar to those already covered or different[31]. This revision introduces a targeted simplification for CDx, namely giving the manufacturers a possibility to reference a group of medicinal products with common characteristics in the intended purpose and associated documentation instead of individually specifying the INNs. The evidence requirements remain unchanged, i.e. manufacturers would still need to justify that their clinical evidence is sufficiently broad to support the use of the CDx with the medicinal products in the group. This justification would still be reviewed by the notified body and the CDx would be subject to a consultation of the medicinal product authorities (unless it is covered by the simplification in the previous section). Therefore, the measure does not affect the safety of the patients. However, it does reduce the administrative burden associated with repeated updates, for example when a new medicinal product with the same mechanism of action and indications is approved and can be safely paired with an existing CDx. By avoiding multiple repetitive dossier revisions and consultations of the medicinal product authorities, the measure delivers cost and time savings for manufacturers and reduces the burden on notified bodies and the medicinal product authorities, while maintaining an appropriate level of oversight of these devices.

Cost savings:

- Based on current data from the study on monitoring the medical device market, and information available on CDx on the US market, a conservative estimate of the number of CDx on the EU market once the transition to the IVDR is completed is around 70. It can be assumed that the addition of similar medicinal products occurs around every two years, which currently trigger conformity assessment costs around **€75,000** and current medicinal product authority consultation costs of **€56,500**, as they are considered to require a new conformity assessment and a new consultation.
- Allowing to reference to a group of medicinal products in the description of CDx intended purpose would reduce the burden related to these updates. Applied to the above CDx volume, this simplification yields an estimated Union-wide cost saving of **€5.5 million per year**.

Given that the CDx market is likely to grow in the future with the greater trends towards personalised medicine, these savings could be even higher.

[31] Team-NB website, *Team-NB Position Paper*.

Proposed measures

3.7. Support mechanisms

3.7.1. Qualification and Classification

The new proposed provisions introduce a coordinated process among competent authorities, supported where necessary by expert panel opinions, to determine whether a specific product or product group falls within the scope of the MDR or IVDR. The new formal advisory mechanism would allow competent authorities, notified bodies, developers or the European Commission to request expert panel advice on a product's regulatory status and proposed classification. The framework also establishes structured consultation channels between Member States and with other EU regulatory agencies (e.g. EMA, ECHA, EFSA and the SoHO Coordination Board) to ensure coherence across related legislative frameworks and to avoid conflicting regulatory outcomes. Moreover, the Commission may adopt legally binding implementing acts to ensure uniform qualification decisions across the Union.

This coordinated Union-level mechanism allows different types of actor to benefit from the scientific and technical expertise available in the expert panels, reduces duplication of work among Member States, and avoids divergent national interpretations, ultimately leading to more legal clarity, smoother operation of the single market and faster and less costly access of devices to market.

The proposal for revision also introduces a structured process for Member State competent authority resolution of classification disputes between manufacturers and notified bodies. It includes consultation of other Member States and consultation of an expert panel in cases of disagreement between them.

For both qualification and classification, decisions of the Member State competent authorities and opinions of the expert panel would be published, increasing transparency and predictability for stakeholders.

This approach ensures a more uniform application of qualification and classification rules across Member States. Manufacturers and innovators, particularly SMEs, would benefit from earlier clarity, fewer disputes and discussions with notified bodies and competent authorities, resulting in devices reaching the market faster, and a more level playing field with other manufacturers.

Notified bodies would also gain efficiency from greater clarity, have more consistent expectations from manufacturers and more harmonised practices among each other, allowing them to use their resources more efficiently.

Member State authorities would also make more efficient use of their resources through this streamlined process and increased transparency of decisions already taken.

Patients would benefit from devices being available on the market sooner, in particular more innovative devices which typically bring qualification or classification challenges.

By establishing a single, coherent, and predictable Union-level mechanism for qualification and classification, the revision enhances legal certainty, accelerates market access, reduces repetitive or parallel assessment across Member States and notified bodies, and reinforces the uniform

implementation of the Regulations. The strengthened coordination mechanisms ensure that decisions are evidence-based, transparent, and consistently applied, thereby supporting a more coherent regulatory environment for manufacturers and authorities alike.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.7.2. Dispute resolution

The current regulatory framework does not provide a structured procedure for resolving disagreements arising from during conformity assessment, such as divergent interpretations of requirements by the manufacturer and the notified body. In the absence of such a mechanism, disputes are handled bilaterally between notified bodies and manufacturers or escalated through litigation, leading to prolonged uncertainty and inefficient use of resources.

The proposed measure introduces a framework allowing manufacturers or notified bodies to raise substantiated disputes before the authority responsible for the notified body. The authority may examine the case, seek clarifications, or request further input from the notified body and other relevant actors. Where the manufacturer is established in another Member State than the notified body, the authority responsible for the notified body must consult the competent authority of the Member State where the manufacturer is established. In duly justified cases, the authority responsible for notified bodies may seek guidance from the MDCG. By providing a structured avenue for resolving disagreements, the revision enhances predictability and legal certainty, offering stakeholders a more reliable basis for planning and compliance. It is expected to generate efficiency gains for manufacturers and notified bodies by limiting prolonged exchanges, appeals, and associated costs, thereby enabling disputes to be settled more swiftly and with fewer administrative burdens.

This mechanism also supports a more aligned and consistent approach across notified bodies, reducing the risk of contradictory interpretations and contributing to more proportionate and balanced application of regulatory requirements.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.7.3. *Early advice to manufacturers and structured dialogue with notified bodies*

Article 61(2) of the MDR currently allows manufacturers of class IIb devices administering a medicinal product and of class III devices to consult expert panels on their clinical development strategy. In practice, however, use of this early advice mechanism has been limited and perceived as disconnected from notified body expectations, which reduces its practical value to manufacturers.

To address these shortcomings, the proposal for revision expands this consultation mechanism into a joint scientific, technical and regulatory advice procedure, where the manufacturer would be able to request advice from a panel consisting of both scientific and technical experts and experts from notified bodies, clarifying expectations also from the conformity assessment perspective. The scope of the procedure is also proposed to be expanded to class IIb or III medical devices and class C or D IVDs.

The expanded early advice would further support manufacturers by giving them broader access to advice from experts and enhance the relevance of the advice by including not only the scientific and

technical but also regulatory perspective. The clinical strategy is one of the most costly and time-consuming aspects of the manufacturer's conformity assessment work. Being able to obtain advice on this early on and including also the regulatory component offers significant benefits to the manufacturer, avoiding potential significant delays and rework for months or even years in cases where the clinical strategy would otherwise be later questioned by the notified body.

Notified bodies would also benefit from this procedure. The advice would be given by experts in their individual capacity and not on behalf of the notified bodies, preserving the independence of the notified bodies. Nevertheless, by participating in the panel, the notified body experts would gain exposure to state-of-the-art developments, benefit from peer exchange and cross-fertilisation of expertise in the panel and enhance their broader competence in assessing similar types of devices in the future. The expanded early advice mechanism would therefore support a more informed and efficient notified body assessment environment.

Considering the regulatory framework as a whole, the greater use of clinical, technical and regulatory expertise available across the sector would support the gradual convergence of expert views on what constitutes an appropriate clinical strategy and appropriate clinical evidence, contributing to greater harmonisation of approaches among manufacturers and notified bodies without compromising notified body independence in individual assessments.

In parallel, the revision aims to formalise and expand the concept of a structured dialogue between manufacturers and notified bodies before and during conformity assessment, by requiring notified bodies to have procedures in place for this. Structured dialogue is a tool intended to be used later in the conformity assessment process compared to the early advice described above. Its objective is to help manufacturer prepare a good quality application for conformity assessment to be submitted to the notified body.

Currently, notified bodies report that applications from manufacturers are frequently incomplete[32], and it is common practice for documentation to go through several cycles of revision by the notified body, which is costly and time-consuming. Structured dialogue between manufacturers and notified bodies is currently already being implemented but in a limited and ad hoc manner in the absence of a clear legal basis. The greater use of structured dialogue under the proposed revision would provide manufacturers with a systematic opportunity to clarify expectations regarding their application and to address issues proactively before formal submission. This is expected to increase the quality of the application and reduce the number of rounds of assessment.

These measures directly respond to stakeholder feedback highlighting that fragmented or late-stage interactions with notified bodies often lead to uncertainty, repetitive reviews, and prolonged certification timelines. By providing more possibilities for advice at an early stage, with an integrated regulatory perspective, and a predictable dialogue process with the notified bodies, the measures would help ensure good quality of manufacturers' applications and a smooth, efficient and predictable conformity assessment framework. This is expected to translate into faster and more efficient market access of devices, with significant cost reductions for manufacturers. The measures are expected to particularly benefit SMEs, which tend to have limited resources and need more support to navigate the regulatory framework. Notified bodies would also benefit from participating in the advice process as described above and be able to use their resources more efficiently due to

[32] GÖG et al. (2022–2025) European Commission website – *Study supporting the monitoring of availability of medical devices on the EU market. The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting.* Data extracted from February 2025.

improved quality of submissions. Patients would ultimately benefit from greater availability of devices on the EU market.

Cost savings:

- The frequency of manufacturers' recourse to early advice and the savings they may experience can vary. Therefore, several scenarios were considered. A base number of 5,500 annual clinical evidence packages was used, of which the majority would be for changes to existing devices and a smaller part for new devices. Assuming that for 50% of new packages and 10% of modified packages the manufacturers would make use of the early advice, that certain proportions of them would benefit from minor, moderate or major savings, and applying a factor to take into account fees for the early advice, annual total savings of **€84.5 million** can be expected. A more conservative scenario with 30% of new packages and 5% of modified packages making use of the early advice delivers a saving of **€46.2 million** per year.
- For structured dialogue, modelled across 5,500 annual applications to notified bodies, higher rate of recourse can be anticipated. With all applications for new devices and 10% of applications for changes using structured dialogue, the measure yields **€101.3 million** in annual savings. A conservative alternative with 80% of applications for new devices and 5% of applications for changes using structured dialogue, savings of **€70 million** per year can be estimated.

This calculation uses rather conservative saving rates of between €40,000 and €250,000 per intervention. In reality the costs of e.g. re-doing a clinical investigation can exceed €1 million. Therefore, some manufacturer savings would be significantly higher than the above estimate. Overall, several factors could either increase or decrease the final savings, so the figures presented should be seen as indicative rather than definitive.

Detailed analysis can be found in Annex IV - Table 18

3.7.4. Regulatory sandboxes

The proposal for introduction of regulatory sandboxes at both national and Union level. At national level, the sandboxes would create new possibilities for controlled development, testing and validation of innovative medical technologies under real-world conditions. At Union level, sandboxes would additionally enable the testing alternative regulatory approaches or practices, supporting a forward-looking assessment of whether existing rules remain appropriate for emerging technologies and alignment with regulatory science.

These mechanisms would offer several benefits for innovation and public health. By enabling early, supervised experimentation, sandboxes would help accelerate responsible development while ensuring that high levels of patient safety and public health protection are maintained through tailored risk-control measures. At the same time, the structured evaluation of regulatory adaptations would support more agile policymaking, help identify potential gaps or bottlenecks in current requirements and provide evidence to inform future regulatory improvements. Importantly, Union-level sandboxes would not permit the placing on the market of non-compliant devices, ensuring that experimentation occurs without compromising patient safety or health.

A range of actors would be able to participate in or contribute to sandbox activities, including manufacturers, notified bodies, healthcare professionals, and other relevant stakeholders. National

competent authorities would supervise the implementation of national sandboxes, while the Commission oversees Union-level initiatives. Expert panels are proposed to play a central advisory role in the design of sandbox plans, ensuring appropriate scientific, technical and regulatory guidance. Both Member States and the Commission would be required to keep the Medical Device Coordination Group informed of sandbox establishment and outcomes, helping foster transparency, learning across jurisdictions, and the potential development of multi-country sandboxes in the future.

Overall, the measure aims to make the EU more agile in addressing the regulatory needs of novel device types, facilitating faster or, in some cases, enabling market access for safe novel technologies and strengthening competitiveness of EU innovators.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.7.5. EMA support scheme to SMEs

The proposed revision introduces an EU-level support scheme to be set up by the EMA in order to strengthen the ability of small and medium-sized enterprises to navigate the medical device and IVD regulatory framework. Many SMEs face structural challenges such as limited regulatory capacity and have particular challenges dealing with complex systems and high volumes of regulatory information. This measure is intended to provide targeted support and access to regulatory knowledge specifically for SMEs.

By improving SMEs' understanding of regulatory requirements, the measure reduces avoidable errors, lowers compliance-related costs, and helps ensure a more even playing field with larger manufacturers. This support is expected to facilitate faster and smoother market access for SMEs, reduce redesigns and repeated submissions, and generate significant cost savings.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.8. Efficiency of notified body designation and monitoring

The proposal for revision introduces a set of targeted measures to improve the efficiency, coherence, and predictability of the oversight system for notified bodies. These measures address both the designation and monitoring of notified bodies, aiming to optimise the use of administrative resources while maintaining a high and uniform level of competence and performance across the Union. By reinforcing coordination structures, the revised framework also strengthens mutual learning and supports a more consistent application of requirements across authorities, thereby facilitating smoother interactions between notified bodies and manufacturers and contributing to more proportionate and predictable implementation.

For the designation process, the authority responsible for notified bodies would become a formal member of the Joint Assessment Team (JAT) besides experts from other Member States and experts nominated by the Commission, to streamline the process and foster harmonisation among the actors involved. This enhances mutual understanding and improves the consistency of assessments, minimising unnecessary duplication of work and communications. As a result, Member States can develop more harmonized expertise and practices, which would, in turn, lead to a more consistent approach among notified bodies and stable expectations for manufacturers.

The proposal for revision strengthens coordination mechanisms between the authorities responsible for notified bodies, including structured exchanges to resolve diverging opinions on the assessment of notified bodies, thus aiming to ensure a uniform level of rigour and reduce procedural delays in reaching consensus.

The monitoring of notified bodies would similarly benefit from enhanced cooperation. JATs would participate in periodic monitoring at least every two years, supporting early identification of systemic issues and promoting harmonised practices across the Union. Monitoring activities would be planned based on the activities of the individual notified body and customised ensuring the continuous compliance is properly verified.

The replacement of the current obligation for full five-year reassessments of all notified bodies with a strengthen central monitoring mechanism would allow authorities and joint assessment teams to focus resources on targeted and "for-cause" reviews, while ensuring full notified bodies compliance is verified. This contributes to a more efficient use of resources authorities and notified bodies and lower administrative costs.

Overall, the proposed measures aim to reinforce coordination and communication between designating authorities, notified bodies, and the Commission. This would enhance harmonisation across Member State designating authorities and downstream alignment of notified bodies' practices, contributing to a more predictable regulatory environment.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.9. Internationalisation and competitiveness

Stakeholders underline that while the medical device market is increasingly global, there are differences between regulatory requirements of the EU and other major jurisdictions. This means that EU manufacturers must often undergo separate processes (depending on notified body practices) under other schemes or lengthier combined processes, reducing the competitiveness of the EU as a base for innovation. In this context, strengthening international regulatory cooperation and alignment becomes essential not only to facilitate global market access but also to generate cost savings for manufacturers by reducing multiplicity of processes. The proposal for revision strengthens international regulatory cooperation and alignment, allowing the Union to participate more effectively in global harmonisation fora such as the IMDRF, enhancing the EU's strategic position in global regulatory cooperation. It also empowers the Commission to conclude administrative arrangements and develop implementing acts to operationalise reliance mechanisms such as the MDSAP.

Participation in international reliance schemes, in which the EU requirements are taken into account, would bring cost and time savings for manufacturers placing devices on the market in several jurisdictions and improve efficiency, predictability, and competitiveness without lowering safety or performance requirements. Notified bodies would also benefit, as reliance reduces the need for parallel or overlapping assessments, duplicative reporting and frees resources for additional assessments and higher-risk products, thereby reducing certification time and possible bottlenecks. Patients would benefit from earlier availability of devices on the Union market.

Cost savings:

This calculation focuses on cost savings for manufacturers interested in using the MDSAP. According to the proposed measures MDR / IVDR requirements could be integrated in MDSAP programme. This would allow manufacturers to undergo only MDSAP process, including a single MDSAP audit, instead of a combined MDSAP+MDR/IVDR audit, receiving a single audit report and having one single scheme to follow to address findings.

- The number of EU manufacturers interested in benefiting from MDSAP reliance varies by enterprise size, ranging from 5% of micro-enterprises to 100% of large and very large manufacturers. Out of about 15,400 notified body clients, the total number estimated to be interested in using MDSAP is about 5,800 manufacturers.

- Estimated cost savings per avoided MDR/IVDR and MDSAP combined approach are on average around **€16,000**. This reduction stems from avoided duplicative processes, reduced preparation and follow-up costs, and decreased documentation and internal resource effort.

- Combining these elements yields average savings of **€92.2** million per year.

In addition to direct audit-related savings, with greater use of MDSAP, EU manufacturers would also avoid substantial opportunity costs from longer conformity assessment times associated with undergoing separate or combined audits processes to access non-EU markets, and consequent postponing or slowing planned expansion into additional jurisdictions. Therefore, the above savings calculation is likely to be an underestimate.

Detailed analysis can be found in Annex IV - Table 19

3.10. Other actions to streamline compliance

3.10.1. Supply chain monitoring

The revision of Article 10a of the Regulations reinforces EU's capacity to anticipate and manage medical device supply disruptions. The new provision strengthens the EU's ability to anticipate and manage shortages of medical devices that could seriously affect patient care. It requires the EMA to set up or further develop an EU-wide IT system dedicated to reporting and exchanging information on interruptions or discontinuations in the supply of medical devices. This system would be interoperable with EUDAMED and would also allow hospitals and healthcare professionals to report situations in which a device is unavailable or at immediate risk of becoming unavailable in their clinical practice.

To ensure that reporting obligations focus on the devices with the greatest potential impact on public health, EMA and the Executive Steering Group on Shortages of Medical Devices (MDSSG) would draw up and publish an EU list of these critical devices or device categories. These proposed measures aim to streamline reporting of potential or actual supply disruptions into a single EU mechanism, reducing duplication for manufacturers and improving coordination and transparency across the Union. It also provides hospitals and users of devices prior information of shortages or possible disruptions that could result in shortages, supporting continuity of care and ensuring continued availability of devices to patients and healthcare systems. The system enables coordinated mitigation when shortages have cross-border consequences and therefore strengthens crisis

preparedness. In conclusion, the proposed amendment aims at a more coherent Union-wide monitoring framework that enhances patient safety, legal certainty, and crisis preparedness, while easing administrative burden on both authorities and manufacturers.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.10.2. Simplified process for measures in emergency situations

The proposed revision strengthens the Commission's capacity to act in emergency situations, allowing for temporary Union-wide derogations where urgent measures are necessary to ensure the availability of critical medical devices or to safeguard public health. This empowerment reflects lessons learned from the COVID-19 pandemic, as reflected also in the targeted evaluation of the MDR and IVDR, when fragmented national derogations led to inconsistent application, parallel administrative procedures, and delayed access to essential devices.

The proposed empowerment enables a faster and more harmonised Union response in emergency situations. By allowing the Commission to adopt temporary and coordinated derogations or regulatory action, the proliferation of parallel or diverging national derogations is avoided and the availability of critical devices during crises can be facilitated. This is further supported by improved coordination among Member States, contributing to more harmonised approaches across the Union. At the same time, the introduction of clear rules for emergency decisions enhances legal certainty for manufacturers and competent authorities, reducing administrative complexity and ensuring predictable implementation. The proposal for revision also promotes more efficient use of resources, as streamlined Union coordination would prevent duplication of assessments and support coherent crisis management efforts.

Overall, this measure strengthens the EU's preparedness and resilience in responding to future health emergencies. It provides a consistent and transparent framework for action, improving both the responsiveness and legal clarity of the regulatory system while safeguarding the continuity of supply for essential medical technologies. This measure is expected to facilitate faster access to the market for manufacturers producing critical medical devices during an emergency, support national competent authorities in taking coordinated decisions, and most importantly provide for continued availability of critical medical devices to healthcare systems and patients in a time of emergency.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

3.10.3. Digital labels

The proposal for revision introduces the possibility for digital labelling of medical devices and IVDs, to be established through a future Commission implementing act, following the model of the existing electronic Instructions for Use (eIFU) Regulation (EU) 2021/2226. This measure would allow certain information currently printed on physical labels to be provided in electronic form, while maintaining essential safety information on the device or its immediate packaging.

A pragmatic, risk-based approach would guide implementation: information critical for safe use and identification would remain physically displayed, whereas other elements, may transition to electronic access.

This measure would be expected to come with several benefits for both manufacturers and users: reduced printing, packaging and distribution costs, faster updates and reduced risk of errors, and potential for improved accessibility for readers such as bigger symbols. Overall, digital labelling supports a more efficient, flexible, and sustainable regulatory framework while improving access to accurate information for patients and healthcare professionals.

Note: While this measure is expected to generate efficiencies and cost savings, these cannot be reliably quantified due to factors such as case by case variation, fluctuations over time or frequency of cases or data complexity and/or availability.

4. CONCLUSIONS

The targeted revision of the MDR and IVDR aims to address the structural challenges observed during implementation, while fully preserving the Regulations' objectives of "a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". Building on the framework's decentralised approach and harmonising the practices of notified bodies and of Member States, the initiative aims for a leaner, more cost-effective, and more predictable system. This would not only lower compliance costs for stakeholders across sectors but would also provide greater certainty, enabling more confident planning of research and development activities. All in all, the measures put forward by the proposal aim to shift from fixed-frequency to risk-based processes, improve proportionality by differentiating more appropriately between lower and high-risk devices, reduce administrative burden and redundances in processes and provide more legal certainty and predictability. Ultimately the proposal aims to ensure continued availability of safe and performant devices for patients.

This analysis provides an overview of cost savings of some of the major measures put forward by the proposal and places particular emphasis on manufacturers, the stakeholder group with the biggest cost saving. In this context, the quantified cost-saving estimates focus on manufacturers and include a breakdown, where possible of savings across micro, small, medium and large enterprises, reflecting the differentiated impact by company size. The available data did not consistently allow for a meaningful assessment of cost reductions expected to also benefit other stakeholder groups, including notified bodies, competent authorities, healthcare institutions or other actors. It should also be noted that certain broader public health benefits—such as faster patient access to innovative technologies, efficiencies resulting from clearer classification rules, and overall system-level improvements—are inherently difficult to quantify. Nonetheless, these impacts are expected to generate meaningful value for patients and healthcare systems and are qualitatively described under each measure, as they cannot be expressed through numerical estimates.

As for the methodology employed for the quantified measures, publicly available data, information provided by manufacturers, notified bodies, national authorities, healthcare institutions and other relevant stakeholders was utilised (see bibliography). As in several cases the data was not always consistent, or available only from a limited number of sources, the results are likely to be an underestimate and should be interpreted with the abovementioned limitations in mind.

Proposed measures aimed at facilitating the generation of clinical or non-clinical evidence include expanding the conditions under which equivalence, based on publicly available information, may be used, and recognises different types of literature, real-world evidence and validated non-clinical or *in silico* methods as acceptable sources of data, among others. In addition, certain simplifications of processes related to performance studies and clinical investigations, as well as administrative simplification related to the summary of safety and (clinical) performance are expected to provide an administrative and financial relief to the sector. Based on stakeholder input, the estimated savings

arising from the measures related to generation of evidence could amount to around €311 million per year.

A significant part of the cost burden under the current framework stems from cyclical activities as part of conformity assessment, such as change management activities, annual activities related to sampling of technical documentation and recertification. The introduction of predetermined change control plans (PCCPs) enables predictable and more efficient handling of foreseeable modifications and associated administrative cost reductions. The most substantial savings arise from replacing systematic sampling of technical documentation with reviews that are carried out when there is a clear reason or risk signal. The precise cost saving calculation is subject to some uncertainties, including variation in manufacturers' portfolio size and composition, sampling intensity and fee variation between notified bodies, and the proportion of reviews that would still be triggered by specific concerns. Nevertheless, the significant reduction in workload associated with this measure is expected to generate savings of a significant order of magnitude. Moreover, the proposal to replace recertification every five years with a lighter periodic review focused on ongoing compliance and post-market performance is expected to provide further relief. The measures also include reduction in frequency of fixed audits, administrative simplification of periodic safety update reporting and reduction in duplication of assessment of serious incidents. Overall, the general conformity assessment measures are estimated to provide around €2.1 billion in savings per year.

In addition to the above, there are several measures specific to particular types of devices. This includes putting in place accelerated conformity assessment pathways for orphan and breakthrough devices. Devices falling under the breakthrough category are estimated to benefit from opportunity-cost savings from faster access to market, estimated at around €570 million per year (figure estimated relying on assumptions about the number of devices that would qualify and the value attributed to earlier market access). Simplification from removal of notified-body involvement for class I reusable surgical instruments (when harmonised standards or common specifications are applied) and class A sterile IVDs, removal of individual technical documentation assessment for near-patient tests, simplified treatment of companion diagnostics covering multiple medicinal products and mandatory fee reductions for micro and small enterprises—50% and 25% respectively—provide further cost combined cost savings of around €122 million per year. Further measures such as grandfathering for certain orphan devices and simplification for devices manufactured and used in a health institution are based on qualitative or semi-quantitative data and are expected to result in further savings.

Furthermore, several cross-cutting measures are expected to enhance predictability and improve coherence across the internal market. Early advice and structured dialogue mechanisms are expected to provide support to manufacturers at early stages of conformity assessment, reducing the likelihood of divergent interpretations or iterative assessments and providing an estimated €146 million in annual savings (figure calculated using assumptions about frequency of their use, individual saving rates and associated fees). Reliance on MDSAP, where appropriate, avoids duplicative administrative processes for manufacturers placing devices on the market in several jurisdictions and could result in around €92 million in annual saving, although this depends on current and future uptake rates. The establishment of a Union-level system for monitoring supply disruptions provides qualitative benefits by reducing fragmented reporting. Several measures also aim to streamline interaction among authorities and between various actors in the conformity assessment framework, such as improved mechanisms for notified body designation and monitoring, resolving qualification and classification issues, disputes in conformity assessment, and regulatory sandboxes. They represent simplifications that are expected to result in increased efficiency of the regulatory framework and savings for many actors in the system.

In conclusion, the targeted revision of the MDR/IVDR represents a strategic initiative aimed at supporting EU competitiveness and innovation, notably providing relief to SMEs, through streamlined conformity assessment and overall functioning of the regulatory system, bringing substantial annual savings. The measures remain fully aligned with the Regulations' objective of ensuring a high level of safety and health, as they simplify requirements in areas where this does not compromise safety or performance. Moreover, competitiveness and innovation are integral to safeguarding high-quality patient care, since patient safety also depends on the timely availability of effective medical devices. By supporting a more efficient and innovation-friendly system, the measures ultimately help ensure that patients continue to have access to the devices they need. Overall, the combined quantifiable impact of the simplification measures described in this document, taking into account the limitations and assumptions outlined throughout, is estimated to reach around €3.3 billion per year, including estimated €0.9 billion in adjustment costs savings and €2.4 billion in administrative cost savings. Alongside financial relief, the measures aim to put in place a proportionate, efficient and flexible framework, increase legal certainty, support more coherent implementation across the Union and sustain the high level of health protection set out in the MDR and IVDR.

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ANNEX I: SYNOPSIS OF STAKEHOLDER CONSULTATION

1. Consultation approach

The Commission conducted a targeted and proportionate stakeholder consultation to inform the revision of the Regulations, in particular in the refinement of the proposed measures and to collect specific evidence on their expected costs savings or potential additional costs incurred.

First, the targeted revision of the Regulations results from the findings of the **targeted evaluation**[33] that has been launched in 2024. The targeted evaluation was informed by extensive consultation activities, including a **Call for Evidence and a Public Consultation** (12 December 2024 to 21 March 2025)[34], which were complemented by **targeted consultation** activities.

Second, to inform the preparation of the simplification proposal a specific **Call for Evidence** was open for feedback from 8 September to 6 October 2025[35]. A total of 427 individual feedback[36] and 166 attachments[37] were considered valid. The final analysis is based on these 427 feedback contributions and 165 attachments[38]. Position papers sent by stakeholders to the European Commission were also taken into consideration.

Third, **targeted consultation activities** have been conducted. This encompassed targeted surveys and/or workshops for the following groups: national competent authorities, large and medium manufacturers, micro and small manufacturers, notified bodies, health institutions.

2. Overview of respondents to the Call for evidence

In terms of **stakeholder groups**, companies and businesses were the largest contributors (199 contributions, 46.6%) followed by business associations (61 contributions, 14.29%). Notified bodies were identified separately (5 contributions, 1.17%). The other represented groups were NGOs (36 contributions, 8.43%), academic / research institutions (31 contributions, 7.26%), public authorities (13 contributions, 3.04%), trade unions (6 contributions, 1.41%) and consumer organisations (1 contribution) as well as from stakeholders that selected 'Others' (30 contributions, 7.03%). A large number of feedback came from **citizens**, including 37 feedback from EU citizens (8.67%) and 8 from non-EU citizens (1.87%).

As part of the participating public authorities, the **scope** varies, with 8 **national** authorities, 4 **regional** authorities and one **local** authority. However, feedback from this group should be interpreted with care as some feedback were submitted by stakeholders representing health providers,

A large majority of contributing companies/businesses represented **SMEs** (129 feedback, 64.8%) with 34 medium-, 54 small-, 41 micro- sized companies.

In terms of **geographical scope**, the respondents to the Call for Evidence were mostly from Germany (100 feedback, 23.42%), Belgium (48 feedback, 11.24%) and France (39 feedback, 9.13%). Other

[33] [Placeholder for SWD Targeted Evaluation, SWD(2025)1051]
[34] European Commission website, *EU rules on medical devices and in vitro diagnostics – targeted evaluation*.
[35] European Commission website, *Medical devices and in vitro diagnostics – targeted revision of EU rules*.
[36] This included 1 contribution discarded as not respecting the feedback rules, 5 contributions from 4 contributors were removed as considered duplicates, and 14 contributions were merged into 6 contributions as considered complementary feedback.
[37] As part of the 171 attachments received in the CFE, 5 were not taken into account in the analysis (1 attachment from the discarded feedback, 2 attachments were part of the above duplicates, and one document was sent 3 times by one contributor (merged contributions)).
[38] The one attachment sent 3 times by one contributor was considered off-topic.

participants were from Sweden (33 feedback, 7.73%) and the Netherlands (31 feedback, 7.26%) followed by respondents from the United Kingdom (22 feedback, 5.15%) and the United States (20 feedback, 4.68%).

3. Stakeholder views:

3.1.General views on the targeted revision

Feedback to the call for evidence indicated that respondents agreed with the identified hurdles stemming from the Regulations. They referred to their disproportionate costs, high administrative burden and overall regulatory complexity, also echoing the findings of the targeted evaluation. Stakeholders showed overall broad support for measures aiming at simplifying and making the regulatory framework more proportionate and efficient, reducing administrative burden, and allowing for more flexibility to support innovative devices to reach the market.

Respondents across all stakeholder groups overall recognized the objectives of the Regulations and stressed that **maintaining safety standards and a high level of public health**, including by ensuring the availability of devices or by supporting innovation for small population groups, should remain at the centre of the revision.

Overall, stakeholders underlined the need for a **risk-based approach to requirements,** supported greater **digitalisation** and a more efficient **governance.** Feedback included proposed changes related to several areas, including clinical and post-market data requirements, **simplification** and greater **predictability** of the **conformity assessment process**, as well as changes related to audits and post-market surveillance

Feedback also particularly emphasized the implications of the Regulations for **SMEs** as costs to comply with the requirements are viewed as particularly disproportionate for SMEs; many stakeholders are asking for SMEs' needs to be taken into account.

3.2. Detailed analysis

The detailed analysis is based on feedback received through the Call for Evidence and other channels.

3.2.1. Legal clarity

Stakeholders stressed the need to clarify **some definitions and terms** in the Regulations to improve the legal clarity of the framework. Examples of terms mentioned in feedback received included intended use and intended purposes, as well as substantial changes, custom-made, patient-matched or mass-produced devices.

Concepts that stakeholders believe should be considered as part of the regulatory framework include well-established technologies, orphan devices and breakthrough devices.

Some stakeholders are also seeing the definition of health institutions unclear and too narrow, asking for a revised definition notably as regards organisations that use devices in clinical trials, and improved coherence with the Clinical Trials Regulation.

3.2.2. Clinical evidence, clinical investigations and performance studies

The need to allow for more flexibility in the requirements for clinical evidence was underlined. Feedback concerned the evidence required as part of clinical investigation and performance studies

but also greater use of evidence generated in the post-market phase (e.g. during post-market clinical follow-up (PMCF).

First, there was feedback calling for a broader recognition of clinical data from equivalent devices, which as a result would allow for more flexibility in the requirements for clinical evidence.

Second, stakeholders across various groups supported broader definition of clinical data and greater guidance and use of non-clinical evidence. Feedback varied in the examples cited, which mainly covered the use of real-world evidence, data from registries, literature data, post-market data, or in-silico methods.

Thirdly some stakeholders argued that the requirements for clinical investigations and for performance studies should be more risk-proportionate

3.2.3. Classification

Stakeholders expressed concerns on the rules related to **the classification of devices** under the Regulations. Stakeholders are calling for more predictability in the classification of devices – including for instance through clearer guidance on certain devices - but also for revised classification rules that are more risk-proportionate. Many contributions underlined challenges in software classification.

3.2.4. Conformity assessments and re-certification

With regards to conformity assessments, contributions across many stakeholder groups underlined the **high costs and lengthy conformity assessment procedures**; representatives of companies, including SMEs, indicated experiencing a lack of predictability and diverse interpretations across notified bodies and competent authorities. Stakeholders are calling for simplification of the conformity assessment procedures and in particular of re-certification of devices.

As part of the proposed measures, some stakeholders advocated for the setting of maximum timelines for conformity assessment.

Some stakeholders also support greater **harmonisation of documentation**. One example suggested further harmonization in the templates and technical documentation required by notified bodies for conformity assessment under the IVDR.

To improve the transparency and predictability of the system, stakeholders also ask for the publication of **transparent information** from notified bodies such as on their **fees** structure, timelines, performance. Other proposed changes were the definition of maximum prices, the set-up of fee systems with premium charges for accelerated procedures, or reduced fees for SMEs.

Furthermore, many stakeholders advocate for **adapted conformity assessment pathways** for special types of devices. Stakeholders indicated different categories of devices to which these specific rules could apply, such as innovative products, especially breakthrough, devices for patients with specific needs (e.g. orphan devices, paediatric devices, niche products), as well as low risk devices.

As part of the suggested changes to streamline the conformity assessment procedures, stakeholders proposed to **simplify the re-certification requirements** for both MDs and IVDs. Various proposals were made in this context, including defining more proportionate requirements for notified body activities during re-certification. Suggestions also included the extension of the certificate duration, permanent validity of certificates or limiting recertification to certain cases subject to criteria. Instead

of regular re-certification cycles, stakeholders proposed to rely on continued post-market surveillance.

3.2.5. Views on specific devices

- **In-house devices**

Stakeholders also underlined the need for measures to simplify the regulatory framework for **in-house devices** manufactured and used by health institutions.

Due to the administrative burdens and costs associated with current framework, stakeholders indicated risks related to reduced development and use of in-house devices by health institutions, leading to reduced access of patients to such devices (e.g. to novel diagnostics for rare diseases, prenatal samples, expansion of personalized medicines), impact on innovation (as some laboratories may discontinue or choose not to develop new devices, etc) or the challenges of rapidly evolving areas and preparedness for crises (e.g. infectious disease diagnostics).

The suggested regulatory changes mainly focused on ensuring proportionate requirements for in-house devices (e.g. Article 5.5, for instance on requirements related to equivalence, on allowing to share devices between laboratories, etc.) and the possibility to rely on international standards (e.g. ISO 15189 for IVDs) instead of the requirements set out in Annex 1 of the Regulation.

- **Software**

The main request (from stakeholders across various groups) in relation to software is a revision of the current classification rules (as per MDR, Rule 11) to allow for their classification as low-risk devices in order to reflect the use of the device and the associated risks. Stakeholders view the current classification system as stringent and disproportionate, with most software being classified Class IIa devices, thus applying the related regulatory requirements to this class of devices. Different classification would lead to proportionate evidence requirements.

Other suggestions covered the development of more expertise on software e.g. for notified bodies.

- **Well-established technologies and grandfathering**.

Stakeholders across various stakeholder groups, mainly the industry, NGOs, notified bodies and some citizens, are calling for more recognition of **well-established technology devices (WET)** in order to make the regulatory system more proportionate for them.

In this context, some feedback underlined the need to **clarify the definition** of WET including to replace the current list of WET, or to define common specifications.

Furthermore, **simplified clinical evaluation requirements and adjusted conformity assessment procedures** were proposed for well-established technologies with low risks or long history of safety.

Stakeholders mainly representing the industry favoured **grandfathering** provisions for both MDs and IVDs, asking to carry over the validity of certificates granted under the Directives to the Regulations, with devices with long safety history, especially low-risk devices, often cited as examples.

3.2.6. Reporting obligations

Several stakeholders are calling for **streamlining of reporting requirements**. Some feedback stressed the perceived high costs associated with meeting these requirements.

Some industry respondents stress the **overlap** between the summary of safety and (clinical) performance with other documents and called for reduction of unnecessary validation and translation of these summaries.

Significant feedback was received regarding **overlapping** requirements in the context of the post-market surveillance and vigilance. Respondents called for reduction in overlap between different post-market surveillance documents such as the Post Market Surveillance plan, Post Market Clinical Follow-Up plan, Post-Market Surveillance Report, the Post-Market Clinical Follow-up Report and the Periodic Safety Update Report, as well as reduced frequency of reporting for lower-risk devices. Notified bodies acknowledged duplication in assessment of serious incidents between competent authorities and notified bodies.

Finally, a few contributions also covered concerns on high frequency of audits, including unannounced audits.

3.2.7. Sampling of technical documentation

Both notified bodies and industry referred to unclear expectations as regards **sampling of technical documentation**, the high costs of this process, especially for SMEs, and its resource-intensive nature for both manufacturers and notified bodies. Respondents called for minimised mandatory sampling, and greater focus on post-market surveillance and changes. Notified bodies also pointed out contradictions between sampling rules and requirements for validation of the summary of safety and (clinical) performance.

3.2.8. Views on support mechanisms

- **Early dialogue**

When it comes to early dialogues, stakeholders, including both large companies and SMEs indicated the need for dialogues with notified bodies (or expert panels on clinical evidence generation prior to submissions, especially for innovative devices. Feedback from notified bodies echoes the possibility to have early dialogues with the industry, indicating that this would enhance the predictability and efficiency of the conformity assessments without lowering the requirements. Some feedback also proposed dialogues with national authorities or the EMA.

- **Regulatory sandboxes**

Stakeholders advocated in general for measures supporting innovation to reach the market. A few of them specifically proposed the introduction of regulatory sandboxes in the regulatory framework.

3.2.9. Digitalisation

Stakeholders from various groups (trade unions, public authorities, business associations) are calling for accelerated and secured deployment and use of **EUDAMED**.

Some stakeholders' feedback also favoured greater **use of digital tools**, proposing the digitalisation of procedures such as digital technical documentations, and audits. Other mentioned the broader availability of electronic instructions for use or digital label.

Stakeholders across various groups stressed some challenges related to **the requirements of unique device identification** (UDI) and highlighted areas for improvement. Company and business association feedback focused on the need for clear guidance on UDI management (including for software changes), overall code formatting and clarifications on UDI direct marking requirements in some cases. Distributors, including pharmacies underscored logistical challenges with UDI requirements sampling obligations, and repackaging rules and related costs. Stakeholders who identified themselves as 'Other' highlighted challenges in fulfilling healthcare institution obligations to store UDI of high-risk implantable devices, including variation in UDI codes and lack of electronic systems leading to difficulties in identifying devices. They also underlined the overall need for improved incident reporting systems.

3.2.10. Governance

Stakeholders also call for an **enhanced governance system**, to help ensure harmonised interpretation of the requirements, predictability, oversight of notified bodies and efficient resolution of disputes. In this perspective, recommendations included improved coordination among governance actors, clearer roles and enhanced accountability.

Some stakeholders specifically referred to a **centralised governance system**, mentioning expected benefits in building expertise and increased confidence in the system. Finally, the involvement of patients in the governance was mentioned in the feedback.

3.2.11. Coherence with other EU legislation

Lastly, stakeholders advocated for measures enhancing the **coherence with other EU legislative frameworks**, among others in the areas of clinical trials, artificial intelligence, access and use of data, and the general data protection regulation as well as use of chemicals and environmental sustainability.

In particular, many stakeholders identified the need to ensure greater harmonisation and alignment of rules governing medical devices and clinical trials, due to diverging timelines, inconsistencies in the requirements or duplications.

ANNEX II: SUMMARY OF COST-SAVINGS

Measure	Savings per year			Type of simplification				Direct benefit[1]				Indirect benefit[2]			Type of cost calculated	
	Conservative	Moderate	High	Type I	Type II	Type III	Type IV	Mnfs	NBs	NCAs	HIs / HCPs	NCAs	Patients	HIs / HCPs	Administrative	Adjustment
Part I																
3-1-1 Use of equivalence, real-world evidence, *in silico* and other methodologies	€164,375,999	€244,939,279	€325,502,559				X	X	X	X			X	X	X	X
3-1-2 Removal of mandatory clinical investigations for Class IIa implantable devices	€6,192,000	€20,640,000	€43,344,000		X			X		X			X	X	X	X
3-2-1 Authorisation and notification of performance studies	€409,786	€795,486	€946,876		X			X		X			X	X	X	
3-2-2 Enable coordinated assessment for combination studies	€260,126	€366,966	€473,806			X		X		X			X	X	X	
3-3 Summary of safety and (clinical) performance	€32,797,867	€44,295,096	€59,822,085		X		X	X	X				X	X	X	X
Part II																
3-4 Simplification and clarification of classification rules		Qualitative			X		X	X	X			X	X	X		X
3-5-1 Change management	€246,298,252	€477,625,608	€708,952,964			X		X	X				X	X	X	
3-5-2 Surveillance frequency	€21,167,533	€63,502,599	€105,837,665	X				X	X						X	
3-5-3 Sampling of technical documentation	€986,475,472	€1,127,400,540	€1,268,325,607		X			X	X						X	
3-5-4 Unannounced audits	€37,666,532	€62,777,553	€87,888,574	X				X	X						X	
3-5-5 Replace 're-certification' by 'periodic review' and duration of certificates	€214,473,549	€227,157,966	€237,684,049			X		X	X						X	
3-5-6 Periodic safety update report (PSUR)	€43,215,178	€53,697,390	€99,435,480	X	X			X	X							X
3-5-7 Analysis of serious incidents	€25,029,331	€50,058,661	€75,087,992			X		X	X	X					X	
3-6-1 Well-established technologies (WET)		Qualitative					X	X	X				X	X	X	X
3-6-2 Class I reusable surgical instrument MDs and Class A sterile IVDs	€12,364,676	€23,283,191	€34,201,706		X			X	X				X	X	X	
3-6-3 Technical documentation of near-patient tests	€2,376,840	€3,377,760	€4,503,680		X			X	X				X	X	X	
3-6-4 In-house devices		Semi-quantitative				X					X		X		X	X
3-6-5 Orphan and breakthrough devices	€227,947,500	€569,868,750	€1,697,200,313				X	X	X				X	X		X
3-6-6 Grandfathering of orphan devices already on the market		Semi-quantitative				X		X	X		X		X		X	X
3-6-7 Fee reductions	€61,092,980	€90,264,855	€122,849,584				X	X					X	X	X	
3-6-8 Companion diagnostics (CDx) consultation		Semi-quantitative						X	X	X			X	X	X	
3-6-9 Companion diagnostics (CDx) - Changes to INNs	€4,602,500	€5,523,000	€7,364,000			X	X	X	X	X			X	X	X	
Part III																
3-7-1 Qualification and classification		Qualitative					X	X	X	X			X	X		X
3-7-2 Dispute resolution							X	X	X	X			X	X	X	
3-7-3 Early advice and structured dialogue	€112,042,000	€145,548,600	€179,055,200				X	X	X				X	X	X	X
3-7-4 Regulatory sandboxes							X	X				X	X	X		X
3-7-5 SME support scheme and EMA support		Qualitative					X	X	X						X	X
3-8 Efficiency of notified body designation and monitoring									X	X					X	
3-9 Internationalisation and competitiveness	€40,356,664	€92,243,803	€144,130,941			X		X	X			X	X	X	X	
3-10-1 Supply chain monitoring						X	X	X		X			X	X	X	X
3-10-2 Simplified measures in emergency situations		Qualitative				X	X	X		X			X	X	X	
3-10-3 Digital labels						X		X							X	X
Total	**€2,239,144,783**	**€3,303,367,102**	**€5,202,607,081**													

Measure	One-off savings			Type of simplification				Direct benefit[1]				Indirect benefit[2]			Type of cost calculated	
	Conservative	Moderate	High	Type I	Type II	Type III	Type IV	Mnfs	NBs	NCAs	HIs / HCPs	NCAs	Patients	HIs / HCPs	Administrative	Adjustment
3-3 Validation of the Summary of safety (and clinical) performance	€15,484,203	€20,742,413	€31,358,929		X	X		X	X				X	X	X	
3-6-3 Technical documentation of near-patient tests	€45,055,200	€67,555,200	€90,055,200		X			X	X				X	X	X	
Total	**€45,055,200**	**€67,555,200**	**€90,055,200**													

[1]Main actors directly benefitting from simplification measure (e.g. reduced costs, reduced repetitive activities).

[2]Main actors indirectly benefitting from simplification measure (e.g. geater availability and variety of devices).

Mnfs = Manufacturers; NBs = Notified bodies; NCAs = National competent authorities; HIs / HCPs = Health institutions / Healthcare professionals.

ANNEX III: DISTRIBUTION OF DEVICES, CERTIFICATES, AND ENTERPRISES

Table 1.1: Device distribution

MD	Distribution		Number of devices	% Implantable	% of the total number of devices needing QMS cert	IVD	Distribution	Number of devices
Class I	27%	44%	239,976	0%	-	**Class A**	21%	25,200
Class Is/m/r		56%	300,024	0%	5%	**Class A sterile**	1%	1,200
Class IIa	31%		620,000	12.5%	40%	**Class B**	49%	58,800
Class IIb	31%		620,000	75%	40%	**Class C**	25%	30,000
Class III	11%		220,000	-	15%	**Class D**	4%	4,800
Total	100%		**2,000,000**		100%	**Total**	100%	**120,000**

This table represents the distribution of the number of devices across various risk classes. The distribution of MDs across risk classes was derived from data extracted from the Italian National Database (Elenco[39]), which was used as a proxy for the Union market[40]. The distribution of IVDs across risk classes is taken from a survey performed by MedTech Europe[41]. This distribution was applied to the total number of IVDs extracted from Elenco[42], with adjustment to the Union market. The Union market adjustment was calculated based on the above understanding that 80% of devices placed on the EU market were also placed on the Italian market. The proportion of class IIa and IIb implantable devices was estimated by selecting the relevant European Medical Device Nomenclature (EMDN) codes out of the total number of devices in the respective risk class. The distribution of devices requiring a QMS certificate was obtained by redistributing the relative proportions of each risk class after removing general class I devices and class A IVDs.

[39] Italian National Database, *Elenco dei dispositivi medici*.
[40] An assessment of possible nomenclatures for future use in the European Medical Device Database was conducted jointly by the Commission and an MDCG TF in 2018. This assessment also looked at the use of various nomenclatures, including the Classificazione Nazionale di dispositivi medici (CND). Based on input received from industry at the time, it was estimated that 80% of devices placed on the EU market were also placed on the Italian market.
[41] MedTech Europe, *Results: Market composition of in vitro diagnostic medical devices (IVDs)*, September 2021.
[42] Refer to footnote 38.

Table 1.2: Certificate distribution

MD	Risk class	Number in "steady state" after transition to Regulations completed (GOEG, applications 02/2025, assume all have applied already)	Breakdown of sampling vs individual technical documentation assessment	% QMS certificates per risk class	Assumption that certificate distribution is same as device number distribution	Number of devices in the Union market (Elenco/0.8= 2M MDs)	Number of devices per certificate
MD QMS	I	0	0	0%	0	239,976	0
	Is/m/r	18,722	11,284	5%	936	300,000	320
	IIa			40%	7,489	620,000	83
	IIb not impl			15%	2,808	155,000	55
	IIb impl		7,438	25%	4,681	470,000	100
	III			15%	2,808	215,000	77
MD TD		7,438					

Company size	Proportion of QMS certificates by company size	Number of QMS certificates by company size	QMS per notified body client	QMS certificates for all Classes except IIb impl and III by company size	QMS certificates for Class IIa by company size	QMS certificates for Class IIb not impl by company size	QMS certificates for Class IIb by company size	QMS certificates for Class IIb non impl by company size
Micro	15%	2,811	1.0	1,694	1,124	424	1,124	422
Small	26%	4,816	1.0	2,903	1,927	726	1,927	722
Medium	27%	5,000	1.5	3,014	2,000	753	2,000	750
Large	29%	5,400	1.9	3,255	2,160	814	2,160	810
Supra large	4%	694	5.0	418	278	105	278	104

IVD	Risk class	Number in "steady state" after transition to Regulations completed (GOEG, applications 02/2025, assume not all have applied yet)	Breakdown of sampling vs individual technical documentation assessment	% QMS certificates per risk class	Assumption that certificate distribution is same as device number distribution	Number of devices in the Union market (Elenco/0.8= 120k IVDs)	Number of devices per certificate
IVD QMS	A	0	0	0.0%	0	25,200	0
	As	1,833	Cannot split by analogy to MDs as transition is not advanced enough	1.3%	24	1,200	50
	B			62.0%	1,137	58,800	52
	C			32.0%	587	30,000	51
	D			5.0%	92	4,800	52
IVD TD		1,439					

Company size	Proportion of QMS certificates by company size	Number of QMS certificates by company size	QMS per notified body client	QMS certificates for Class B by company size	QMS certificates for Class C by company size
Micro	17%	304	1.0	188	97
Small	28%	521	1.0	323	167
Medium	26%	469	1.3	290	150
Large	25%	465	1.6	288	149
Supra large	4%	75	5.0	47	24

These tables provide an overview of the estimated number of certificates distributed across device risk classes (tables on the left) and company size (tables on the right). As a starting point for the tables, the number of certificate applications were taken from GÖG et al. (2022–2025) dashboard[43].

- *For MDs (top left table): the numbers of applications were considered as representative of the "steady state" number of certificates when the transition to the MDR is fully completed (as the transition timelines are quite advanced).*
- *For IVDs (bottom left table): a factor was applied to account for future applications (as there are several years in the transition left).*

The estimates of the "steady state" QMS certificates were then further distributed according to device risk class as per table 1.1.

[43] GÖG et al. (2022–2025) European Commission website – *Study supporting the monitoring of availability of medical devices on the EU market. The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting*. Data extracted from February 2025.

- *For medical devices, the number of QMS certificates for class IIb implantable and class III devices was assumed to be the same as the number of product certificates for them.*

The distribution of QMS certificates by company size in the tables on the right was obtained based on an assumption that the number of QMS certificates increases with company size (i.e., smaller manufacturers would have fewer manufacturing sites and thus fewer QMS certificates than larger manufacturers). This number was then further broken down by device risk class using the proportions from table 1.1.

Note: The distribution of certificates across risk classes assumes that certificates cover devices of different classes separately. In reality, a certificate can cover devices falling under multiple risk classes (e.g. QMS certificate covering both IIa and IIb non-implantable devices). This assumption was necessary to be able to analyse certain device class specific measures.

Table 1.3: Enterprise distribution

Total manufacturers (MD+IVD)				MD manufacturers requiring notified body involvement				Cost of audit	IVD manufacturers requiring notified body involvement			
Total number of manufacturers (MTE)	High-level manufacturer distribution (MTE)	Distribution breakdown (National associations)	Number of manufacturers per enterprise size	Number of notified body clients (GOEG)	High-level client distribution (Team-NB)	Distribution breakdown (GOEG backend)	Number of clients per enterprise size		Number of notified body clients (GOEG)	High-level client distribution (Team-NB)	Distribution breakdown (GOEG backend)	Number of clients per enterprise size
38,000	90%	43%	16,340	13,875	79%	20%	2,811	20,000	1,500	79%	20%	304
		33%	12,540			35%	4,816	50,000			35%	521
		14%	5,320			24%	3,334	50,000			24%	360
	10%	9%	3,420		21%	20.0%	2,775	75,000		21%	20%	300
		1%	380			1.0%	139	100,000			1%	15

This table represents the distribution of manufacturers placing devices on the Union market, distributed across manufacturer size. Left side represents the total number of manufacturers. Right side represents the number requiring notified body involvement.

The total number of manufacturers and the distribution (90/10) made available by MedTech Europe[44] was taken into consideration. A more detailed breakdown by company size (micro, small, medium and large) was obtained taking into consideration the more detailed distributions collected by several national industry associations across Europe. The number of notified body clients was derived from GÖG et al. (2022–2025)[45], while Team-NB data[46] was used to establish the high-level distribution of clients across manufacturer groups (79/21). The more detailed distribution of notified body clients by company size was obtained using data from notified bodies.

[44] MedTech Europe, *Facts and Figures 2025*.
[45] Refer to footnote 42.
[46] Team NB, *Medical Device Survey 2024 Data from all 41 designated members*, 2024.

ANNEX IV: DETAILED CALCULATIONS

Generation of Evidence and Procedures for Performance Studies and Clinical Investigations

Table 1: Use of equivalence, real-world evidence, in silico and other methodologies

Number of MD clinical evidence packages/year
5,000

Number devices: class III and	761,875
Number devices: IIa and IIb non-	703,125
Total	1,465,000

							Conservative		Moderate		High	
	Cost of establishing clinical evidence	Number of devices	Proportion of devices	Number of packages	Current cost	Cost saving per package	Adoption rate of saving	Saving	Adoption rate of saving	Saving	Adoption rate of saving	Saving
New class III and implantable	€1,500,000	114,281	7.8%	390	585,057,594 €	50%	10%	29,252,880 €	20%	58,505,759 €	30%	87,758,639 €
New IIa and IIb non-impl	€500,000	105,469	7.2%	360	179,980,802 €	50%	10%	8,999,040 €	20%	17,998,080 €	30%	26,997,120 €
Modif class III and implantable	€250,000	647,594	44.2%	2,210	552,554,394 €	50%	30%	82,883,159 €	40%	110,510,879 €	50%	138,138,599 €
Modif class IIa and IIb non-impl	€125,000	597,656	40.8%	2,040	254,972,803 €	50%	30%	38,245,920 €	40%	50,994,561 €	50%	63,743,201 €
Total		1,465,000	100.0%	5,000	1,572,565,593 €			**159,380,999 €**		**238,009,279 €**		**316,637,559 €**

Number of IVD clinical evidence packages/year
300

					Conservative		Moderate		High	
	Cost of establishing clinical evidence	Number of packages	Current cost	Cost saving per package	Adoption rate of saving	Saving	Adoption rate of saving	Saving	Adoption rate of saving	Saving
New IVDs	€300,000	45	13,500,000 €	30%	10%	405,000 €	20%	810,000 €	30%	1,215,000 €
Modif IVDs	€200,000	255	51,000,000 €	30%	30%	4,590,000 €	40%	6,120,000 €	50%	7,650,000 €
Total		300	64,500,000 €			**4,995,000 €**		**6,930,000 €**		**8,865,000 €**

	Conservative	Moderate	High
Total MD+IVD	**164,375,999 €**	**244,939,279 €**	**325,502,559 €**

These tables estimate the cost saving from greater use of equivalence, real-world evidence and other methodologies for the generation of clinical evidence for medical devices and IVDs. The following parameters have been estimated with stakeholder and expert input: the number of clinical evidence packages per year, the costs per package, the relative proportions of packages generating evidence for new versus modified devices, and the expected saving from the use of these methodologies per package. The distribution of packages per class was based on the distribution of device classes (see table 1.1 in Annex III). Three scenarios of adoption rates were considered (conservative, moderate and high) with the understanding that modified devices would likely be able to benefit more from these methodologies than new devices.

Table 2: Removal of mandatory clinical investigations for class IIa implantable devices

											Conservative	Moderate	High
# of clinical investigations in 2024	# of clinical investigations for Class IIa impl (lower)	# of clinical investigations for Class IIa impl (average)	# of clinical investigations for Class IIa impl (upper)	Cost of a clinical investigation per patient enrolled	# of patients enrolled in clinical investigations for Class IIa impl (lower)	# of patients enrolled in clinical investigations for Class IIa impl (average)	# of patients enrolled in clinical investigations for Class IIa impl (upper)	Cost of a clinical investigation for Class IIa impl (lower)	Cost of a clinical investigation for Class IIa impl (average)	Cost of a clinical investigation for Class IIa impl (upper)	Total cost saving (lower)	Total cost saving (average)	Total cost saving (upper)
1032	21	41	62	€10,000	30	50	70	€300,000	€500,000	€700,000	**€6,192,000**	**€20,640,000**	**€43,344,000**

This table estimates the cost savings resulting from the removal of mandatory clinical investigation requirement for class IIa implantable devices.

- *The total number of clinical investigations for all risk classes conducted across Europe[47] in 2024 was used as a baseline, based on data collected from national competent authorities.*
- *Stakeholder and expert input supported the estimation of the share of these investigations attributed to class IIa implantable devices, with three estimates used (low, average and high).*
- *An average enrolment cost per patient was estimated.*
- *Three estimates were made for the number of patients typically enrolled in class IIa implantable clinical investigations.*

On the basis of these parameters, the total cost of such investigations was modelled across three scenarios, calculating the savings under conservative, moderate and high estimates.

[47] Data collected included responses from non-EU Member States such as countries in the European Economic Area (EEA).

Table 3: Authorisation and notification of performance studies

Industry saving:												
Number of studies (industry)	Average number of Member States per study (industry)	Internal admin costs of sponsor for study with average # of Member States (lower)	Internal admin costs of sponsor for study with average # of Member States (average)	Internal admin costs of sponsor for study with average # of Member States (upper)	Number of applications per year (Member States)	Number of studies (CAs)	Average number of studies (both sources)	Average fee per Member State	Total fees for study with average number of Member States	Saving industry (lower)	Saving industry (average)	Saving industry (upper)
5.6	4.675	€10,745.43	16,118 €	21,491 €	42	9.0	7.3	2,336 €	10,919 €	**157,976 €**	**197,154 €**	**236,331 €**

Competent authority resource saving:			
Number of performance studies (both sources)	Average number of Member States per study (industry)	Average cost of processing per Member States	Saving national resources
7.3	4.675	€2,239	**76,335 €**

	Conservative	Moderate	High
Total (industry + national resources)	**234,311 €**	**273,489 €**	**312,667 €**

	Conservative	Moderate	High
Total (industry + national resources)	**409,786 €**	**795,486 €**	**946,876 €**

Industry saving:							
Number of notifications per year (CAs)	Average sponsor internal cost per Member State (lower)	Average sponsor internal cost per Member State (average)	Average sponsor internal cost per Member State (upper)	Average fee per Member State	Saving industry (lower)	Saving industry (average)	Saving industry (upper)
276	€813.13	1,220 €	1,626 €	267 €	**298,171 €**	**410,383 €**	**522,595 €**

Competent authority resource saving:		
Number of notifications per year (CAs)	Average cost of processing per Member State	Saving national resources
276	404 €	**111,615 €**

	Conservative	Moderate	High
Total (industry + national resources)	**409,786 €**	**521,998 €**	**634,210 €**

These tables estimate the cost savings linked to the simplification of authorisation and notification processes for certain performance studies.

For routine blood draw performance studies, the average number of Member States involved per study was based on industry data. The number of such studies conducted annually across the EU was determined based on data both from national competent authorities and industry. Industry and expert input provided estimates of the administrative costs for sponsors per study (under three scenarios, lower, average and upper). Data from competent authorities was used to determine the average fee per Member State and the average cost of processing an application. Using these inputs, total cost savings for both industry and competent authorities were calculated under low, median, and upper scenarios.

A similar approach was applied to companion diagnostic notifications, but the average number of Member States was not required due to the individual nature of notifications.

Table 4: Coordinated assessment for clinical performance studies and clinical investigations that are also part of clinical trials

										Conservative	Moderate	High
Number of authorisation requests per year	Out of these, those linked to a clinical trial	% requests linked to clinical trial	Average # of Member States per study	Number of studies linked to a clinical trial	Sponsor internal admin cost for study with average # of Member States (lower)	Sponsor internal admin cost for study with average # of Member States (average)	Sponsor internal admin cost for study with average # of Member States (upper)	Estimate of fees for study with average # of Member States	Estimated cost saving from single process instead of separate processes	Saving (lower)	Saving (average)	Saving (upper)
477	371	78%	5.6	66	10,745	16,118	21,491	2,336 €	30%	**260,126 €**	**366,966 €**	**473,806 €**

This table estimates the cost savings arising from the coordinated assessment of clinical performance studies that are also part of a clinical trial.

Data provided by competent authorities was used to determine the annual Union-wide number of authorisation requests, as well as the share of these requests linked to clinical trials. The average number of Member States involved per study, the range of the administrative costs for the sponsor and the average Member State fee were assumed to be the same as in the analysis of routine blood draw performance studies above. Industry consultations resulted in the selection of an estimated 30% reduction in costs when studies are conducted as a combined process rather than separate procedures. This reduction factor was applied to the costs, resulting in total savings across the conservative, moderate and high saving scenarios.

Table 5: Summary of safety and clinical performance (SSCP) and Summary of safety and performance (SSP)

# of Class IIa and IIb non impl PSURs	Percentage that are Class IIa implantable	# of SSCPs for Class IIa implantable	# of SSCPs for IIb impl and III	Total # of SSCPs	Validation (Low fee)	Validation (Median fee)	Validation (High fee)	Update/Re-validation (Low fee)	Update/Re-validation (Median fee)	Update/Re-validation (High fee)	Total validation costs (Low fee)	Total validation costs (Median fee)	Total validation costs (High fee)	Total update/re-validation costs (Low fee)	Total update/re-validation costs (Median fee)	Total update/re-validation costs (High fee)
9,079	7%	649	6,603	7,252	€2,076	€2,745	€4,068	€1,697	€2,407	€3,624	€13,775,143	€18,214,243	€26,992,911	€11,260,317	€15,971,469	€24,046,782

MD+IVD	Total saving validation (Low fee)	Total saving validation (Median fee)	Total saving validation (High fee)
	€15,484,203	**€20,742,413**	**€31,358,929**

MD+IVD	Total saving update/re-validation (Low fee)	Total saving update/re-validation (Median fee)	Total saving update/re-validation (High fee)
	€14,525,558	**€19,932,018**	**€29,368,238**

# of Class C and D PSURs	N/A	# of SSPs for Class C subject to sampling	# of SSPs for Class D and Class C not sampling	Total # of SSPs	Validation (Low fee)	Validation (Median fee)	Validation (High fee)	Update/Re-validation (Low fee)	Update/Re-validation (Median fee)	Update/Re-validation (High fee)	Total validation costs (Low fee)	Total validation costs (Median fee)	Total validation costs (High fee)	Total update/re-validation costs (Low fee)	Total update/re-validation costs (Median fee)	Total update/re-validation costs (High fee)
1,506	N/A	67	1,439	1,506	€1,185	€1,675	€3,674	€2,264	€2,624	€4,478	€1,709,060	€2,528,171	€4,366,018	€3,265,241	€3,960,549	€5,321,456

	Conservative	Moderate	High
MD+IVD	Total costs (Low fee)	Total costs (Median fee)	Total costs (High fee)
	€48,282,070	**€65,037,509**	**€91,181,014**

Total # of SSCPs	Proportion of SSCPs destined to HCP and patient	# of SSCPs destined to HCP and patient	Fraction of pages for patient	Fraction of pages for removal of duplication with IFU	Cost of drawing up SSCP	Cost of translation	Total costs (lower)	Total costs (median)	Total costs (upper)	Total saving (lower)	Total saving (median)	Total saving (upper)
7,252	16%	1,168	20%	N/A	€6,000	€50,000	€42,000	€56,000	€70,000	€9,813,709	€13,084,945	€16,356,181

MD+IVD	Total saving (lower)	Total saving (median)	Total saving (upper)
	€18,272,308	**€24,363,078**	**€30,453,847**

Total # of SSPs	Proportion of SSPs destined to HCP and patient	# of SSPs destined to HCP and patient	Fraction of pages for patient	Fraction of pages for removal of duplication with IFU	Cost of drawing up SSP	Cost of translation	Total costs (lower)	Total costs (median)	Total costs (upper)	Total saving (lower)	Total saving (median)	Total saving (upper)
1,506	13%	193	20%	30%	€3,000	€20,000	€17,250	€23,000	€28,750	€8,458,600	€11,278,133	€14,097,666

These tables estimate the cost savings associated with the simplification of validation, update/re-validation, and reduction in the number of pages of SS(C)Ps. More than one device can be covered under the same SS(C)P. The grouping of devices under SS(C)Ps was assumed to be the same as under PSURs in the table below. The scope of SS(C)Ps and PSURs differs in the coverage of class IIa devices. Taking this into account, the number of SS(C)Ps was derived based on the number of PSURs and the distribution of devices per risk class in Annex III.

The top two tables focus on cost savings from removing the validation requirement. Based on data retrieved from notified bodies and industry, lower, median, and upper fee estimates for validation and update/re-validation were applied to determine the corresponding total cost savings.

The bottom two tables focus on the cost savings due to the reduction in the number of pages of SS(C)Ps. The number of SS(C)Ps destined to healthcare professionals and patients, the estimated fraction of pages that would be removed, and the cost of drafting and translating SS(C)Ps were estimated based on industry and expert input. For IVDs, an additional cost saving was calculated based on the reduction of pages due to removal of duplication with the instruction for use.

Elements of conformity assessment

Table 6: Change management

			Cost per change for QMS				Cost saving		
Enterprise size	**QMS certificates per company size**	**Changes to QMS certificate***	**Low**	**Average**	**High**	**Cost saving**	**Low**	**Average**	**High**
Micro	2,811	0	**€10,000**	**€17,500**	**€25,000**	30%	€0	€0	€0
Small	4,816	1					€14,449,147	€25,286,007	€36,122,867
Medium	5,000	2					€30,002,877	€52,505,034	€75,007,192
Large	5,400	3					€48,601,562	€85,052,733	€121,503,904
Supra-large	694	5					€10,406,250	€18,210,938	€26,015,625

			Cost per change for TD				Cost saving		
Enterprise size	**TD certificates**	**Changes to TD certificate***	**Low**	**Average**	**High**	**Cost saving**	**Low**	**Average**	**High**
All	7,438	2	**€25,000**	**€52,500**	**€80,000**	30%	€111,570,000	€234,297,000	€357,024,000

Total MD	**Lower**	**Average**	**Higher**
	€215,029,835	**€415,351,711**	**€615,673,587**

	Conservative	**Moderate**	**High**
Total MD+IVD	**Lower**	**Average**	**Higher**
	€246,298,252	**€477,625,608**	**€708,952,964**

IVD specific change management:

			Cost per change for QMS				Cost saving		
Enterprise size	**QMS certificates per company size**	**Changes to QMS certificate***	**Low**	**Average**	**High**	**Cost saving**	**Low**	**Average**	**High**
Micro	304	0	**€10,000**	**€17,500**	**€25,000**	30%	€0	€0	€0
Small	521	1					€1,562,070	€2,733,622	€3,905,175
Medium	469	2					€2,811,080	€4,919,391	€7,027,701
Large	465	3					€4,186,934	€7,327,134	€10,467,334
Supra-large	75	5					€1,125,000	€1,968,750	€2,812,500

			Cost per change for TD				Cost saving		
Enterprise size	**TD certificates**	**Changes to TD certificate***	**Low**	**Average**	**High**	**Cost saving**	**Low**	**Average**	**High**
All	1,439	2	**€25,000**	**€52,500**	**€80,000**	30%	€21,583,333	€45,325,000	€69,066,667

Total IVD	**Lower**	**Average**	**Higher**
	€31,268,417	**€62,273,897**	**€93,279,377**

These tables estimate the cost savings resulting from the introduction of predetermined change control plans (PCCPs) for changes related to both QMS and product certificates.

- *The total number of QMS certificates per enterprise size for both MDs and IVDs was derived from the tables in Annex III.*
- *The number of changes per year which would currently require notified body assessment, and the estimate of the proportion of costs saved from the use of PCCPs was estimated based on industry and expert input.*
- *The range of costs per change was estimated based on notified body and industry data.*

The cost savings were estimated based on conservative, moderate and high scenarios corresponding to the range of costs per change.

Table 7: Surveillance frequency

	Audit cost calculation:	Audit costs lower	Audit costs median	Audit cost higher
Micro and small	planning costs + conduct (number of auditors x FTE days) + travel costs + report fees	7,500 €	13,750 €	20,000 €
Medium		25,000 €	37,500 €	50,000 €
Large		50,000 €	85,000 €	120,000 €
	Number of certificates:			
Micro and small	8,452	63,391,516 €	116,217,779 €	169,044,042 €
Medium	3,694	92,351,197 €	138,526,796 €	184,702,394 €
Large	3,229	161,437,500 €	274,443,750 €	387,450,000 €
	Currently:			
	Total per year n	317,180,213 €	529,188,325 €	741,196,437 €
	Corrected due to combined activities (MDSAP etc)	253,744,170 €	423,350,660 €	592,957,149 €
	In the future:			
	Total per year n	253,744,170 €	423,350,660 €	592,957,149 €
	Total per year n+1 with 10% fewer audits	228,369,753 €	381,015,594 €	533,661,434 €
	Total per year n+1 with 30% fewer audits	177,620,919 €	296,345,462 €	415,070,005 €
	Total per year n+1 with 50% fewer audits	126,872,085 €	211,675,330 €	296,478,575 €
	Savings per year:			
	With 10% fewer audits	12,687,209 €	**21,167,533 €**	29,647,857 €
	With 30% fewer audits	**38,061,626 €**	**63,502,599 €**	**88,943,572 €**
	With 50% fewer audits	63,436,043 €	**105,837,665 €**	148,239,287 €

This table estimates the cost savings related to the measure on reducing the frequency of surveillance audits.

The costs of audits broken down by enterprise size were obtained based on data collected from industry, notified bodies and expert input.

To calculate the current costs of yearly surveillance audits, the above costs were applied to the distribution of QMS certificates per enterprise size from Annex III. An adjustment was applied to capture combined activities (such as MDR audits also covering MDSAP audits).

Three scenarios were estimated to capture the potential cost savings if there would be 10%, 30% or 50% fewer audits every other year.

Table 8: Sampling of technical documentation

Super large	Typical number of categories/ groups in a portfolio	Current TDs reviewed per category per surveillance (lower)	Current TDs reviewed per category per surveillance (median)	Current TDs reviewed per category per surveillance (upper)	Sampling costs	Number of QMS certs of that class and that mf size	Current costs of surveillance per year (lower)	Current costs of surveillance per year (median)	Current costs of surveillance per year (upper)
MDs	5	1	3	5	€36,000	382	€68,681,250	€206,043,750	€343,406,250
IVDs	4	1	3	5	€36,000	71	€10,152,000	€30,456,000	€50,760,000
Total							**€78,833,250**	**€236,499,750**	**€394,166,250**

Large	Typical number of categories/ groups in a portfolio	Current TDs reviewed per category per surveillance (lower)	Current TDs reviewed per category per surveillance (median)	Current TDs reviewed per category per surveillance (upper)	Sampling costs	Number of QMS certs of that class and that mf size	Current costs of surveillance per year (lower)	Current costs of surveillance per year (median)	Current costs of surveillance per year (upper)
MDs	3	1	2	3	€36,000	2,970	€320,770,307	€641,540,613	€962,310,920
IVDs	2	1	2	3	€36,000	437	€31,485,742	€62,971,483	€94,457,225
Total							**€352,256,048**	**€704,512,097**	**€1,056,768,145**

Medium	Typical number of categories/ groups in a portfolio	Current TDs reviewed per category per surveillance (lower)	Current TDs reviewed per category per surveillance (median)	Current TDs reviewed per category per surveillance (upper)	Sampling costs	Number of QMS certs of that class and that mf size	Current costs of surveillance per year (lower)	Current costs of surveillance per year (median)	Current costs of surveillance per year (upper)
MDs	3	1	2	3	€36,000	2,750	€297,028,480	€594,056,960	€891,085,440
IVDs	2	1	1.5	2	€36,000	440	€31,708,986	€47,563,479	€63,417,973
Total							**€328,737,466**	**€641,620,439**	**€954,503,412**

Micro & Small	Typical number of categories /groups in a portfolio	Current TDs reviewed per category per surveillance (lower)	Current TDs reviewed per category per surveillance (median)	Current TDs reviewed per category per surveillance (upper)	Sampling costs	Number of QMS certs of that class and that mf size	Current costs of surveillance per year (lower)	Current costs of surveillance per year (median)	Current costs of surveillance per year (upper)
MDs	1	1	1	1	€36,000	4,195	€151,026,421	€151,026,421	€151,026,421
IVDs	1	1	1	1	€36,000	775	€27,904,636	€27,904,636	€27,904,636
Total							**€178,931,057**	**€178,931,057**	**€178,931,057**

		4 years out of 5-year certificaiton cycle			Per year		
		Conservative	Moderate	High	Conservative	Moderate	High
	Saving factor	Lower	Median	Upper	Lower	Median	Upper
Current costs	N/A	**€938,757,822**	**€1,761,563,343**	**€2,584,368,864**	**€751,006,257**	**€1,409,250,674**	**€2,067,495,092**
Savings (70%)	70%	€657,130,475	**€1,233,094,340**	€1,809,058,205	€525,704,380	**€986,475,472**	€1,447,246,564
Savings (80%)	80%	€751,006,257	**€1,409,250,674**	€2,067,495,092	€600,805,006	**€1,127,400,540**	€1,653,996,073
Savings (90%)	90%	€844,882,040	**€1,585,407,009**	€2,325,931,978	€675,905,632	**€1,268,325,607**	€1,860,745,582

These tables estimate the cost savings associated with removing the routine sampling of technical documentation for review as part of the surveillance activities conducted by notified bodies.

Notified body, industry and expert input were used to determine the typical number of device categories or groups in a portfolio, broken down by manufacturer size, as well as an average cost of assessing one technical documentation file as part of sampling.

The number of QMS certificate holders for each enterprise size and device risk class subject to sampling was derived from the distributions in Annex III.

The cost savings per surveillance year were estimated assuming that between 10-30% of the technical documentation sampling activities would still take place as "for-cause" assessments of the notified bodies, i.e. the savings would be between 70% and 90% of current costs.

The cost saving from reduction in technical documentation sampling during a re-certification year (year 5 in the certification cycle) is taken into account in the re-certification calculation below. To avoid double-counting, the above yearly savings are therefore adjusted to cover 4 out of the 5 years of the current certification cycle.

Table 9: Unannounced audits

Number certificate holders (QMS MD+IVD)	Company size	Number of certificate holders by company size (MD+IVD)	Audit duration	Number of auditors	Audit base cost (lower)	Audit base cost (median)	Audit base cost (upper)	Audit cost per company size (lower)	Audit cost per company size (median)	Audit cost per company size (upper)	Conservative Total (lower)	Moderate Total (median)	High Total (upper)
20,555	Micro+Small	8,452	1.0	1	€8,690	€12,215	€17,448	€8,690	€12,215	€17,448	€73,449,636	€103,239,807	€147,478,120
	Medium	5,469	1.5	2				€26,070	€36,644	€52,345	€142,576,644	€200,403,785	€286,276,917
	Large	6,634	2.0	2				€34,760	€48,858	€69,794	€230,602,650	€324,131,939	€463,022,651
		20,555								**Per 5-year cycle**	€446,628,930	€627,775,531	€896,777,689
										Per year	**€89,325,786**	**€125,555,106**	**€179,355,538**
										30% saving	€26,797,736	**€37,666,532**	€53,806,661
										50% saving	**€44,662,893**	**€62,777,553**	**€89,677,769**
										70% saving	€62,528,050	**€87,888,574**	€125,548,876

	MDs			IVDs			MD+IVD
Number of respondents	25			8			33
	Lower	Median	Upper	Lower	Median	Upper	
Audit fees	5,330	6,430	9,060	7,640	9,460	13,550	
Weighted average	**€5,890**	**€7,165**	**€10,148**				
Travel costs	2,800	5,050	7,300				
Total	€8,690	€12,215	€17,448				

This table estimates the cost savings resulting from the shift from mandatory unannounced audits to a needs-based, "for-cause" approach.

The total number of QMS certificates for MDs and IVDs was taken from the distribution tables in Annex II, together with the breakdown by manufacturer size. Industry data was used to estimate audit duration, the number of auditors typically involved per audit, and the base audit cost. These parameters were used to calculate the total audit cost per manufacturer size under three cost saving scenarios.

Based on these costs, three estimated cost savings scenarios were used (ranging from 30% to 70% savings over a five-year cycle), reflecting varying degrees of reduction in unannounced audit activity.

Table 10: Replace "re-certification" by "periodic review" and remove general limit of duration of certificates

	Enterprise size	Distribution	QMS certificates (GOEG)	Current costs (audit)	Cost today (audit)	10% savings (Administrative saving)
MDR QMS	Micro (<10 employed)	15%	2,671	€20,000	€53,413,082	€5,341,308
	Small (10–49)	26%	4,576	€50,000	€228,778,155	€22,877,815
	Medium (50–249)	27%	4,750	€50,000	€237,522,774	€23,752,277
	Large (≥250)	29%	5,130	€75,000	€384,762,363	€38,476,236
	Supra large	4%	659	€100,000	€65,906,250	€6,590,625
	Total Union wide	100%	17,786		**€970,382,624**	**€97,038,262**

Class IIb impl and III	Enterprise size	Distribution	TD certificates (GOEG)	Current costs (TD)	Factor for re-cert	Cost today (TD)	10% savings (Administrative saving)	50% saving	60% saving	70% saving
MDR TD	All	100%	7,438	€75,000	75%	**€418,387,500**	**€41,838,750**	**€209,193,750**	**€251,032,500**	**€292,871,250**

	MDR QMS (-sampling)	MDR TD	MDR Total (-QMS sampling)
Savings 10%QMS + (10+50%)TD	€97,038,262	€251,032,500	€348,070,762
Savings 10%QMS + (10+60%)TD		€292,871,250	€389,909,512
Savings 10%QMS + (10+70%)TD		€334,710,000	€431,748,262

				5 year cycle			Per year		
				Conservative	Moderate	High	Conservative	Moderate	High
Total (MDR+IVDR)	QMS sampling (60%)	QMS sampling (70%)	QMS sampling (80%)	Total (lower)	Total (medium)	Total (upper)	Total (lower)	Total (medium)	Total (upper)
€415,237,269	€563,254,693	€657,130,475	€751,006,257	€978,491,962	€1,072,367,744	€1,166,243,526	€195,698,392	€214,473,549	€233,248,705
€478,659,352				€1,041,914,045	€1,135,789,828	€1,229,665,610	€208,382,809	€227,157,966	€245,933,122
€531,289,769				€1,094,544,462	€1,188,420,244	€1,282,296,026	€218,908,892	€237,684,049	€256,459,205

	Enterprise size	Distribution	QMS certificates (GOEG)	Current costs (audit)	Cost today (audit)	10% savings (Administrative saving)
IVDR QMS	Micro (<10 employed)	15%	272	€20,000	€5,434,134	€543,413
	Small (10–49)	26%	466	€50,000	€23,275,408	€2,327,541
	Medium (50–249)	27%	483	€50,000	€24,165,067	€2,416,507
	Large (≥250)	29%	522	€75,000	€39,144,912	€3,914,491
	Supra large	4%	67	€100,000	€6,705,163	€670,516
	Total Union wide	100%	1,810		**€98,724,684**	**€9,872,468**

Class D, C self-test, CDx	Enterprise size	Distribution (Team-NB)	TD certificates (GOEG)	Current costs (TD)	Factor for re-cert	Cost today (TD)	10% savings (Administrative saving)	50% saving	60% saving	70% saving
IVDR TD	All	100%	1,439	€100,000	75%	**€107,916,667**	**€10,791,667**	**€53,958,333**	**€64,750,000**	**€75,541,667**

	IVDR QMS (-sampling)	IVDR TD	IVDR Total (-QMS sampling)
Savings 10%QMS + (10+50%)TD	€2,416,507	€64,750,000	€67,166,507
Savings 10%QMS + (10+60%)TD		€86,333,333	€88,749,840
Savings 10%QMS + (10+70%)TD		€97,125,000	€99,541,507

These tables estimate the cost savings from replacing current re-certification practices with 'periodic review'. This calculation assumes that current re-certification activities are merged with annual surveillance for that year and therefore involve an audit and sampling of technical documentation.

The costs of audits as part of re-certification activities increase with manufacturer size, with the values based on industry data and expert input. Conversely, the costs of product certificates are manufacturer size agnostic. Therefore, the distribution of QMS certificates by manufacturer size and the total number of product certificates in Annex III were used to determine the total costs of re-certification.

Audits are likely continuing to happen with the proposed new measure, therefore the estimated cost saving from this aspect of re-certification activity is a 10% saving related to administrative costs of re-issuing the certificate.

As regards product certificates, the current cost was assumed to be 75% of the initial cost of certification. The cost saving expected from the lower depth of reassessment of technical documentation during periodic review was estimated to range between 50-70%, in addition to the 10% saving in administrative costs.

The contribution to the saving from the sampling of technical documentation is calculated using the costs from Table 8 but applying a lower savings range of 60-80% taking into account that there are likely to be additional activities by the notified body (e.g. checking if any new standards are consistently applied). These savings are expected to occur once every certification cycle, i.e. every 5 years. Yearly figures are also provided.

Table 11: Periodic safety update reports (PSUR)

Device class	# of unique PSURs reported by 26 NBs (17th NB survey)	Adjustment for total number of NBs	Proportion of Class IIa devices	Class IIa PSURs	Class IIb non impl PSURs	Current cost of update PSUR (lower)	Current cost of update PSUR (median)	Current cost of update PSUR (upper)
Class IIa and IIb non impl	2,647	9,079	80%	7,263	1,816	€25,984,456	€31,377,456	€45,758,790
Class III and impl	4,402	6,603	N/A	N/A	N/A	€36,646,650	€47,145,420	€109,147,590
						€62,631,106	€78,522,876	€154,906,380

Cost for update	Lower	Median	Upper
Class IIa and IIb non impl	€4,770	€5,760	€8,400
Class III and impl	€5,550	€7,140	€16,530

Device class	Future cost of update PSUR (lower)	Future cost of update PSUR (median)	Future cost of update PSUR (upper)
Class IIa and IIb non imp	€4,330,743	€5,229,576	€7,626,465
Class III and impl	€18,323,325	€23,572,710	€54,573,795
Totals	€22,654,068	€28,802,286	€62,200,260

Device class	Cost saving (lower)	Cost saving (median)	Cost saving (upper)
Class IIa and IIb non imp	€21,653,713	€26,147,880	€38,132,325
Class III and impl	€18,323,325	€23,572,710	€54,573,795
Total (MD)	**€39,977,038**	**€49,720,590**	**€92,706,120**

	Conservative	Moderate	High
Total MD+IVD	**Cost saving (lower)**	**Cost saving (median)**	**Cost saving (upper)**
	€43,215,178	**€53,697,390**	**€99,435,480**

Device class	# of unique PSURs reported by 5 NBs (17th NB survey)	Adjustment for total number of NBs	Current cost of update PSUR (lower)	Current cost of update PSUR (median)	Current cost of update PSUR (upper)
Class C	502	1,506	€4,789,080	€5,783,040	€8,433,600
Class D	152	456	€1,687,200	€2,170,560	€5,025,120
			€6,476,280	€7,953,600	€13,458,720

Cost of update	Lower	Median	Upper
Class C	€3,180	€3,840	€5,600
Class D	€3,700	€4,760	€11,020

Device class	Future cost of update PSUR (lower)	Future cost of update PSUR (median)	Future cost of update PSUR (upper)
Class C	€2,394,540	€2,891,520	€4,216,800
Class D	€843,600	€1,085,280	€2,512,560
Totals	€3,238,140	€3,976,800	€6,729,360

Device class	Cost saving (lower)	Cost saving (median)	Cost saving (upper)
Class C	€2,394,540	€2,891,520	€4,216,800
Class D	€843,600	€1,085,280	€2,512,560
Total (IVD)	**€3,238,140**	**€3,976,800**	**€6,729,360**

This table estimates the cost savings from the simplification measures for PSURs.

The number of PSURs was based on notified body data and was distributed across device risk classes that require them, in accordance with the distribution tables in Annex III.

The internal manufacturer cost estimates for updating the PSURs were based on expert input and were applied to calculate the current total cost for each device class. Estimated future costs were then calculated using the same cost estimate ranges, but with a halved update frequency (or removal for class IIa devices). The estimated cost savings were established for both MDs and IVDs under conservative, moderate and high scenarios.

Table 12: Analysis of serious incidents

Costs of assessment of individual serious incidents that would not be assessed by notified bodies (MDs)							
Total # of reports using EEA numbers as reference	Proportion of serious incident reported that get evaluated (17th NB survey)	Cost per report (MTE survey) (lower)	Cost per report (MTE survey) (average)	Cost per report (MTE survey) (upper)	Total costs for serious incident reporting (EEA multiplier) (lower)	Total costs for serious incident reporting (EEA multiplier) (average)	Total costs for serious incident reporting (EEA multiplier) (upper)
144,299	83.33%	€200	€400	€600	**€24,049,774**	**€48,099,548**	**€72,149,321**

Costs of assessment of individual serious incidents that would not be assessed by notified bodies (IVDs)							
Total # of reports using EEA numbers as reference	Proportion of serious incident reported that get evaluated (17th NB survey)	Cost per report (MTE survey) (lower)	Cost per report (MTE survey) (average)	Cost per report (MTE survey) (upper)	Total costs for serious incident reporting (EEA multiplier) (lower)	Total costs for serious incident reporting (EEA multiplier) (average)	Total costs for serious incident reporting (EEA multiplier) (upper)
4,898	100%	€200	€400	€600	**€979,557**	**€1,959,114**	**€2,938,670**

	Conservative	Moderate	High
Total MD+IVD	Total (lower)	Total (average)	Total (upper)
	€25,029,331	**€50,058,661**	**€75,087,992**

These tables estimate the cost savings associated with limiting notified body involvement in the assessment of serious incidents.

- *The number of MD and IVD serious incident reports in 2024 was collected from EEA national competent authorities (covering 90% of EEA population for MDs and 70% of EEA population for IVDs). This number was adjusted to cover the total EEA population.*
- *The proportion of serious incident reports that are currently evaluated by notified bodies was provided by notified bodies.*
- *The fees of notified body assessment per report were provided by a report from MedTech Europe[48].*

The costs saving estimates are provided in conservative, moderate and high scenarios.

Note: The notified body fees for in-depth assessment of serious incidents that require further evaluation (e.g., serious incidents of high severity or leading to field safety corrective actions) were not taken into account, as these current costs would remain in the future.

[48] MedTech Europe, IVDR & MDR Survey Results 2024, December 2024.

Table 13: Class I reusable surgical instruments and Class A sterile IVDs

Certificate distribution	Elenco	Number of Class I RSI	Current costs			Cost savings		
Number of Class Ir/s/m QMS certificates	Proportion of RSI in Class I		Cost of certificate (lower bound)	Average cost	Cost of certificate (higher bound)	Total costs (lower bound)	Average cost	Total costs (higher bound)
936	74.7%	699	17,100	32,200	47,300	**11,957,126**	**22,515,758**	**33,074,389**

Certificate distribution	Current costs			Cost savings		
Number of Class As QMS certificates	Cost of certificate (lower bound)	Average cost	Cost of certificate (higher bound)	Total costs (lower bound)	Average cost	Total costs (higher bound)
24	17,100	32,200	47,300	**407,550**	**767,433**	**1,127,317**

Total savings		
Conservative	Moderate	High
12,364,676	**23,283,191**	**34,201,706**

These tables estimate the cost savings associated with removing notified body involvement for class I reusable surgical instruments and class A sterile IVDs where manufacturers apply relevant harmonised standards or common specifications.

The number of QMS certificates for class Ir/s/m MDs and class A IVDs was taken from the certification distribution table in Annex III.

- *For MDs, the proportion of reusable surgical instruments within class Ir/s/m MDs was derived from the Elenco database[49].*
- *For IVDs, the proportion of class As IVDs was from industry data.*

Expert input was used to estimate the current costs, taking into account application fees, assessment and audit costs, certificate decision costs and annual fees. These allowed for the calculation of the total costs currently associated with notified body involvement and, consequently, the total cost savings expected under the revised approach for both class Ir MDs and class As IVDs.

[49] Refer to footnote 38.

Table 14: Technical documentation of near-patient tests

	# near-patient tests	# QMS certificates B and C	% QMS with near-patient tests	# QMS of near-patient tests	Near-patient test technical documentation sampled per QMS certificate
Total	1,500	1,723	10%	172	1.2
Per year 3%	50			6	
Per year 5%	75			9	
Per year 7%	100			11	

Total	Cost of technical documentation assessment	Current total cost	Future total cost	Saving
Lower	35,000 €	52,500,000 €	7,444,800 €	**45,055,200 €**
Average	50,000 €	75,000,000 €	7,444,800 €	**67,555,200 €**
Upper	65,000 €	97,500,000 €	7,444,800 €	**90,055,200 €**

Per year	Cost of technical documentation assessment	Current total cost per year (3%)	Current total cost per year (5%)	Current total cost per year (7%)	Future total cost per year (3%)	Future total cost per year (5%)	Future total cost per year (7%)	Saving (3%)	Saving (5%)	Saving (7%)
Lower	35,000 €	1,750,000 €	2,625,000 €	3,500,000 €				1,501,840 €	**2,252,760 €**	3,003,680 €
Average	50,000 €	2,625,000 €	3,750,000 €	5,000,000 €	248,160 €	372,240 €	496,320 €	**2,376,840 €**	**3,377,760 €**	**4,503,680 €**
Upper	65,000 €	3,500,000 €	4,875,000 €	6,500,000 €				3,251,840 €	**4,502,760 €**	6,003,680 €

These tables estimate the cost savings related to the assessment of technical documentation for near-patient tests.

The top table estimates the number of near-patient tests (taken from the 2021 MTE-CAMD survey[50]), the number of corresponding QMS certificates (assuming that they represent 10% of the total number of QMS certificates for class B and C IVDs), and the number of technical documentation files expected to be sampled per certificate. To estimate the yearly saving, the expected number of new near-patient tests per year was calculated assuming they could represent 3% to 7% of the total number of near-patient tests on the market.

The middle table calculates the one-off saving associated with the transition of near-patient tests to the IVDR. Cost parameters for the assessment of technical documentation were based on notified body data and expert input. Based on these inputs, the current and future total costs of technical documentation assessment were calculated for three scenarios.

The bottom table calculates the analogous yearly saving ranges associated with new near-patient tests placed on the EU market.

[50] MedTech Europe, *Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies*, September 2021.

Table 15: Breakthrough devices

														Conservative	Moderate	High
Scenario	Case study	Proportion of similar BtX	# of BtX per year	Device price (lower)	Device price (average)	Device price (upper)	Average units sold months 1-3 (lower)	Average units sold months 1-3 (average)	Average units sold months 1-3 (upper)	Earlier market access (months) (average)	Cost saving for one company (lower)	Cost saving for one company (average)	Cost saving for one company (higher)	Union cost saving (lower)	Union cost saving (average)	Union cost saving (upper)
1	Large manufacturer, Class IIb/III implantable (e.g., three chamber implantable pacemaker)	30%	83	€3,000	€5,000	€7,500	1,000	1,500	3,000	3	€9,000,000	€22,500,000	€67,500,000	€222,750,000	€556,875,000	€1,670,625,000
2	Medium manufacturer, Class IIb/III non-implantable (e.g., continuous glucose monitor)	25%		€100	€150	€200	300	500	1,000		€90,000	€225,000	€600,000	€1,856,250	€4,640,625	€12,375,000
3	Small manufacturer, Class IIa non-implantable, (e.g., finger-prick glucose measuring)	45%		€25	€50	€75	1,200	1,500	1,700		€90,000	€225,000	€382,500	€3,341,250	€8,353,125	€14,200,313
														€227,947,500	**€569,868,750**	**€1,697,200,313**

This table estimates the cost savings from the introduction of an accelerated conformity assessment pathway for breakthrough devices. The estimated cost savings represent opportunity costs, deriving from earlier market access. The number of breakthrough-designated devices that could achieve certification per year was estimated to be around 80, based on numbers from the US market. Simulations based on representative devices and manufacturer sizes were conducted, modelling their price and volumes sold. Opportunity-cost savings were calculated in the conservative, moderate and high saving scenarios.

Table 16: Fee reductions

Lower									
Class	**Proportion of micro per class**	**# applications from micro per year**	**Proportion of small per class**	**# applications from small per year**	**Cost of conformity assessment (micro)**	**Cost of conformity assessment (small)**	**Factor reduction (micro)**	**Factor reduction (small)**	**Cost saving**
Ir	32%	240	32%	412	Covered by another measure				
Ir/m/s	20%	150	15%	193	€15,000	€37,500	50%	25%	€2,935,012
IIa & IIb non impl	45%	338	50%	643	€42,000	€64,500			€17,465,565
IIb impl	2%	15	2%	26	€71,250	€93,750			€1,137,878
III	1%	8	1%	13	€71,250	€93,750			€568,939
	100%	751	100%	1,286					**€22,107,394**

Average									
Class	**Proportion of micro per class**	**# applications from micro per year**	**Proportion of small per class**	**# applications from small per year**	**Cost of conformity assessment (micro)**	**Cost of conformity assessment (small)**	**Factor reduction (micro)**	**Factor reduction (small)**	**Cost saving**
Ir	20%	150	20%	257	Covered by another measure				
Im/s	10%	75	10%	129	€20,000	€50,000	50%	25%	€2,358,640
IIa & IIb non impl	65%	488	65%	836	€56,000	€86,000			€31,640,063
IIb impl	4%	30	4%	51	€95,000	€125,000			€3,034,341
III	1%	8	1%	13	€95,000	€125,000			€758,585
	100%	751	100%	1,286	€266,000	€386,000			**€37,791,629**

Upper									
Class	**Proportion of micro per class**	**# applications from micro per year**	**Proportion of small per class**	**# applications from small per year**	**Cost of conformity assessment (micro)**	**Cost of conformity assessment (small)**	**Factor reduction (micro)**	**Factor reduction (small)**	**Cost saving**
Ir	14%	105	14%	180	Covered by another measure				
Ir/m/s	6%	45	6%	77	€25,000	€62,500	50%	25%	€1,768,980
IIa & IIb non impl	70%	526	67%	862	€70,000	€107,500			€41,555,321
IIb impl	7%	53	10%	129	€118,750	€156,250			€8,144,991
III	3%	23	3%	39	€118,750	€156,250			€2,844,695
	100%	751	100%	1,286					**€54,313,987**

Total (MD+IVD)	
Lower	€61,092,980
Average	€90,264,855
Upper	€122,849,584

Lower									
Class	Proportion of micro per class	# applications from micro per year	Proportion of small per class	# applications from small per year	Cost of conformity assessment (micro)	Cost of conformity assessment (small)	Factor reduction (micro)	Factor reduction (small)	Cost saving
As	1%	8	5%	71	Covered by another measure				
B	89%	738	81%	1,150	€42,000	€64,500			€34,039,187
C	10%	83	14%	199	€42,000	€64,500	50%	25%	€4,946,398
D	0%	0	0%	0	€90,000	€112,500			€0
	100%	829	100%	1,420					**€38,985,586**

Average									
Class	Proportion of micro per class	# applications from micro per year	Proportion of small per class	# applications from small per year	Cost of conformity assessment (micro)	Cost of conformity assessment (small)	Factor reduction (micro)	Factor reduction (small)	Cost saving
As	1%	8	5%	71	Covered by another measure				
B	80%	663	80%	1,136	€56,000	€86,000			€42,991,544
C	18%	149	14%	199	€56,000	€86,000	50%	25%	€8,451,843
D	1%	8	1%	14	€120,000	€150,000			€1,029,839
	100%	829	100%	1,420					**€52,473,226**

Upper									
Class	Proportion of micro per class	# applications from micro per year	Proportion of small per class	# applications from small per year	Cost of conformity assessment (micro)	Cost of conformity assessment (small)	Factor reduction (micro)	Factor reduction (small)	Cost saving
As	1%	8	2%	28	Covered by another measure				
B	65%	539	60%	852	€70,000	€107,500			€41,755,076
C	31%	257	33%	469	€70,000	€107,500	50%	25%	€21,587,313
D	3%	25	5%	71	€150,000	€187,500			€5,193,208
	100%	829	100%	1,420					**€68,535,597**

These tables estimate the cost savings for reduction of notified body fees for micro and small enterprises, by 50% for micro enterprises and 25% for small enterprises.

The number of micro and small manufacturers estimated in Annex III is further distributed by device risk class. Three scenarios were created to explore the impact of variation in the device distributions for micro and small enterprises that require notified body involvement (lower: higher proportion of lower risk classes, average and higher – increasing proportions of higher risk classes).

The cost of conformity assessment per device risk class and company size was based on the costs of audit and the costs of product certificate (for device risk classes that require them) as explained in the recertification measure above (Table 10), and the cost of one technical documentation sampling as referred to in the measure on sampling (Table 8).

Table 17: Companion diagnostics (CDx) – Changes to INNs

Number of CDx	INN additions per CDx per year	Cost of change: conf assessment (lower)	Cost of change: conf assessment (average)	Cost of change: conf assessment (upper)	Cost of change: consultation	Cost per CDx (lower)	Cost per CDx (average)	Cost per CDx (upper)	Union-wide cost (lower)	Union-wide cost (average)	Union-wide cost (upper)
70	0.5	€60,000	€75,000	€90,000	€56,500	€58,250	€65,750	€73,250	€4,077,500	**€4,602,500**	€5,127,500
	0.6					€69,900	€78,900	€87,900	**€4,893,000**	**€5,523,000**	**€6,153,000**
	0.8					€93,200	€105,200	€117,200	€6,524,000	**€7,364,000**	€8,204,000

This table estimates the cost savings associated with additions of medicinal products with similar characteristics to the intended purpose of a companion diagnostic (CDx).

- *The estimated number of CDx on the EU market was derived from the current number of CDx transitioning to the IVDR, adjusted with a factor for the expected number of CDx in the near future, as well as data from the US market.*
- *The typical number of INN additions per device per year was derived from industry input and analysis of data from CDx authorised in the US over a period of time.*
- *The estimated cost of an addition of a medicinal product was estimated to be similar to the cost of conformity assessment, with a lower, average and upper cost. The fees for the EMA consultation were added.*

The estimated cost savings were calculated for conservative, moderate and high scenarios.

Cross-cutting simplification, streamlining processes and harmonisation of activities

Table 18: Early advice and structured dialogue

Early advice				
Number of CE packages MD	5000			
Number of CE packages IVD	300			
Total number of CE packages	5300			
	Proportion:	**Number:**		
New packages	15%	**795**		
Modified packages	85%	**4505**		
New packages going for advice	50%	397.5		
Modified packages going for advi	10%	450.5		
Total packages going for advice		**848**	**Savings:**	
% minor savings	20%	169.6	50,000 €	8,480,000 €
% moderate savings	60%	508.8	100,000 €	50,880,000 €
% major savings	20%	169.6	250,000 €	42,400,000 €
			Total	**101,760,000 €**
			Reduction for fees:	20%
			Final:	**81,408,000 €**
New packages going for advice	30%	238.5		
Modified packages going for advi	5%	225.25		
Total packages going for advice		**463.75**	**Savings:**	
% minor savings	20%	92.75	50,000 €	4,637,500 €
% moderate savings	60%	278.25	100,000 €	27,825,000 €
% major savings	20%	92.75	250,000 €	23,187,500 €
			Total	**55,650,000 €**
			Reduction for fees:	20%
			Final:	**44,520,000 €**

Structured dialogue (SD)				
Number of applications per year MD	5000			
Number of applications per year IVD	300			
Total number of applications	5300			
	Proportion:	**Number:**		
New applications	15%	795		
Modification applications	85%	4505		
New applications going for SD	100%	795		
Modification applications going for S	10%	450.5		
Total applications going for SD		**1245.5**	**Savings:**	
% minor savings	20%	249.1	40,000 €	9,964,000 €
% moderate savings	60%	747.3	100,000 €	74,730,000 €
% major savings	20%	249.1	150,000 €	37,365,000 €
			Total	**122,059,000 €**
			Reduction for fees:	20%
			Final:	**97,647,200 €**
New applications going for SD	80%	636		
Modification applications going for S	5%	225.25		
Total applications going for SD		**861.25**	**Savings:**	
% minor savings	20%	172.25	40,000 €	6,890,000 €
% moderate savings	60%	516.75	100,000 €	51,675,000 €
% major savings	20%	172.25	150,000 €	25,837,500 €
			Total	**84,402,500 €**
			Reduction for fees:	20%
			Final:	**67,522,000 €**

These tables estimate the cost savings associated with the introduction of early advice and structured dialogue as support mechanism.

The calculations for the two tables were analogous.

The estimated total number of clinical evidence packages (for early advice) was taken from the analysis for the clinical evidence measure above, and the number of certificate applications (for structured dialogue), as well as the proportions of packages or applications for new devices vs modified ones were estimated from industry and expert input.

Different scenarios were calculated with different proportions of new and modified packages or certificate applications making use of the early advice or structured dialogue, respectively. The savings that could be achieved in individual cases were stratified by minor, moderate and major savings.

A 20% reduction was applied to account for fees for either mechanism.

Table 19: Internationalisation and competitiveness

							Conservative	Moderate	High
Enterprise size	**# manufacturers (MD+IVD notified body clients)**	**Percentage benefiting from MDSAP**	**# benefiting from MDSAP**	**Cost saving* (lower bound)**	**Cost saving* (average)**	**Cost saving* (upper bound)**	**Future savings (lower)**	**Future savings (average)**	**Future savings (upper)**
Micro	3,115	5%	156				€1,090,295	€2,492,104	€3,893,912
Small	5,337	10%	534				€3,735,951	€8,539,315	€13,342,680
Medium	3,694	50%	1,847	€7,000	€16,000	€25,000	€12,929,168	€29,552,383	€46,175,599
Large	3,075	100%	3,075				€21,525,000	€49,200,000	€76,875,000
Supra-large	154	100%	154				€1,076,250	€2,460,000	€3,843,750
	15,375		5,765						
*Cost saving is the difference between MDSAP audit and MDSAP+MDR audit.						**Total savings**	**€40,356,664**	**€92,243,803**	**€144,130,941**

This table estimates the cost savings associated with the use of reliance mechanisms such as MDSAP, where a combined MDSAP-MDR audit with separate reporting requirements would be replaced by a single MDSAP audit and report.

The estimated number of manufacturers was taken from the enterprise distribution table in Annex III and combined with the estimated proportion of them expected to benefit from MDSAP reliance. For each manufacturer size, the difference between the cost of an MDSAP audit and report and the combined cost of an MDSAP and MDR audit and separate reports was used to calculate estimated cost savings under conservative, moderate and high scenarios.