

BVMed and VDGH White Paper on the Future Development of the MDR and IVDR

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1	INTRODUCTION	2
2	EXECUTIVE SUMMARY	6
3	SUPPLEMENT MISSING REGULATIONS	6
3.1	FAST TRACK PROCEDURE FOR INNOVATIONS.....	6
3.2	ORPHAN DEVICES AND DIAGNOSTICS FOR RARE DISEASES.....	9
3.3	NICHE PRODUCTS.....	11
4	MEASURES TO INCREASE EFFICIENCY AND IMPLEMENTATION OF PRINCIPLES OF GOOD ADMINISTRATION	13
4.1	INTRODUCTION	13
4.2	PREDICTABILITY OF DEADLINES	14
4.3	CALCULABILITY OF COSTS.....	17
4.4	ACCESS TO THE SYSTEM.....	20
4.5	TRANSPARENCY OF NOTIFIED BODY PROCEDURE AND SURVEILLANCE	23
4.6	SUBSTANTIAL CHANGE.....	27
4.7	SYSTEM-INHERENT POSSIBILITY TO COMPLAIN	28
4.8	LEGAL REVIEW OF DECISIONS.....	30
4.9	OVERLAPPING EU LEGISLATION AND NATIONAL LEGISLATION.....	33
5	REFORM OF CERTIFICATION CYCLE.....	35
5.1	REFORM OF (RE-)CERTIFICATION PROCESS OF MDR AND IVDR DEVICES.....	35
5.2	POST MARKET SURVEILLANCE	41
6	INTERNATIONAL COOPERATION AND RELIANCE.....	43
6.1	EU PARTICIPATION IN THE MDSAP	43
6.2	INTERNATIONAL RELIANCE	45
7	CENTRALISATION OF RESPONSIBILITY	49
7.1	STRUCTURING OF CERTIFICATION PROCEDURES AND SELF-CERTIFICATION	49

1 Introduction

Europe is at a crossroads with its market access system for medical devices. By now it is becoming clear that the MDR and IVDR risk not delivering on its promise of a "sound, transparent, predictable and sustainable regulatory framework" that "ensures a high level of safety and health protection" and "at the same time promotes innovation".¹

In 2012 the Commission found that the medical devices regulatory system was "considered as not sufficiently efficient and effective".² This has not improved since. The functioning of the MDR and IVDR still compromises patient and user safety as well as the good functioning of the internal market. Severe and persisting issues relating to the MDR and IVDR transitional regime and application of new procedures lead to shortages of medical devices and IVDs. Many manufacturers have had to rationalize product portfolios as a result of costs for MDR and IVDR compliance, adapt devices to meet MDR and IVDR requirements and experienced significant changes in their supply chains as a result of required changes to devices. Many manufacturers are struggling to find notified body capacity available to re-certify devices again under the MDR and IVDR criteria, which were already safe and effective. As a result of lack of direction of notified bodies the emphasis in conformity assessment is put on procedural minutiae and requirement box-ticking, rather than assessment of the manufacturer's ability to reliably manufacture the device(s) concerned in his QMS.

The current system slows the pace of innovation. The MDR and IVDR rules are experienced as complex and unpredictable, making it less appealing to develop and launch novel products in Europe.³ This is compounded by other factors, including Brexit and intense reimbursement pricing pressure, which may also reduce the attractiveness of pursuing the CE mark. This has resulted in a situation where the US market has emerged as the preferred launch site for new medical technology while, historically, medtech companies preferred to launch in Europe because they viewed EU product registrations as more straightforward.⁴

The governance of the medical devices system in the Union is fragmented, as a result of which there is no concentration of responsibility for the functioning of the system in one place, resulting in many parties taking part in the system but none of them

¹ Recital 1 MDR and IVDR

² Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 4

³ Boston Consulting Group, "Interstates and Autobahns: Global Medtech Innovation and Regulation in the Digital Age", March 2022, p. 5

⁴ Boston Consulting Group, "Interstates and Autobahns: Global Medtech Innovation and Regulation in the Digital Age", March 2022, p. 5

taking responsibility for its overall functioning and performance. Industry welcomes the established system based on certification by Notified Bodies as third-party, independent institutions, which has functioned very well for decades and has proven its legitimacy and efficiency under the Directives. Like the other stakeholders notified bodies have invested massively in MDR and IVDR implementation and are facing problems related to lack of harmonized policy and delayed MDR / IVDR roll-out.

In the meantime at national levels health institutions find themselves in the situation that medical devices are often not available to the market. Data from April 2022 show that more than 50% of the medical devices companies are planning portfolio reductions, affecting 33% of these companies' devices as planned for discontinuation.⁵ For IVDs 17% of today's IVD total market will be discontinued, of which 50% is discontinued by small and medium sized enterprises (SMEs).⁶ SMEs turn out to be impacted more by the MDR⁷ and IVDR⁸ than larger companies, although they represent 95% of the medical devices and IVD manufacturers in Europe. Discontinuation decisions taken by many SMEs largely are based on the expectation that the IVDR remediation cost will outweigh the product revenue.⁹ This happens on top of the devices that have already been discontinued since the entry into force of both regulations on 26 May 2017 and regardless of the additional legacy devices expected to be discontinued by the end of the grace periods for the MDR and IVDR in case their transition to the MDR or IVDR is unsuccessful. This will have a significant impact on healthcare systems. National parliaments are putting more and more pressure on local government to intervene in the excesses and shortages caused by a regulated market driven approval mechanism for medical devices.

At the moment we have not achieved the robust regulatory framework promised in the Impact Assessment for the MDR and IVDR that would be adapted to present and future technical and scientific progress, would contain clearer rules, more easily to be followed by economic operators and to be implemented by national authorities, and would provide the necessary instruments for a sustainable, efficient and credible management at EU level.¹⁰ The regulated commercial partnership between notified bodies and manufacturers based on a civil law certification agreement is currently not calibrated under the MDR and IVDR to the efficiency with which it functioned under the Directives preceding the MDR and IVDR. Notified bodies struggle with the

⁵ MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 3

⁶ Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8

⁷ MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 7

⁸ Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8

⁹ Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8

¹⁰ Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 12

additional responsibilities under the MDR and IVDR and the restrictions on possibilities for meaningful dialogue with manufacturers.

With the January 2022 amendment to the IVDR¹¹ and the March 2023 amendments to the MDR¹² transitional regimes the EU has bought more time for notified bodies to complete conformity assessment of the enormous reservoir of applications clogging the system. Manufacturers are obliged to delay introduction of innovations to the European market where they can already apply make them available in other markets. This results in a situation where European patients are worse off, and manufacturers will need to incur additional costs in supporting older versions of devices for the European market only.

Furthermore, structural issues that create compounding inefficiencies in the system or violate principles of good administration that could have been resolved before the initial entry into force of the MDR and IVDR still persist. The principles of good administrative practice developed in the case law under the European Convention of Human Rights and the EU's own Human Rights Charter are incorporated in the MDR and IVDR by reference but none have been operationalised.¹³ In short, the overall objectives of the MDR and IVDR have not been met at this stage.¹⁴

This paper occasionally refers to the EU medicinal products framework as a reference point for implementation of good administrative practice for market access of healthcare products. Given the fact that medical devices and IVDs fulfil an essential role in the healthcare system like medicinal products do there is no objective justification why medical devices and IVDs should be treated differently when it comes to application of principles of good administration.

¹¹ Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices, OJ 2022 L19/3

¹² Regulation 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices, OJ 2023 L080/24

¹³ See recital (89) MDR and IVDR: "This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles."

¹⁴ Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 6: "This revision pursues three overall objectives:

- Overall objective A: To ensure a high level of protection of human health and safety
- Overall objective B: To ensure the smooth functioning of the internal market
- Overall objective C: To provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry"

This White Paper does not aim to provide fixed solutions but aims to start a discussion on how to make the MDR and IVDR future-proof beyond the quick fixes and ‘delays’ by proposing potential options for the further development of the regulatory system for medical devices after the final transition from the Directives to MDR and IVDR and ensure their full implementation, in the short, mid and long term:

Option	Short term (1 year)	Mid term (2-4 years)	Long term (>5 years)
3.1 Fast Track Procedure for Innovations		X	
3.2 Orphan Devices and diagnostics for rare diseases regime	X	X	
3.3 Niche products regime	X	X	
4.2 Predictability of deadlines	X	X	
4.3 Calculability of the costs	X		
4.4 Access to the system	X	X	
4.5 Transparency of notified body procedure and surveillance	X		
4.6 Substantial Change definition	X		
4.7 System-inherent possibility to complain	X		
4.8 Legal review of decisions	X (option 2)	X (option 1)	
4.9 Overlapping legislation and national legislation	X		
5.1 Reform of re-certifications of MDR and IVDR products	X	X	X
5.2 Post market surveillance more pragmatic	X	X	
6.1 EU participation in the MDSAP	X	X	
6.2 International reliance		X	
7.1 Structuring of certification procedures and self-certification		X	X

2 Executive summary

While there is broad agreement that the foundations of the EU system are sound, all stakeholders seem to agree at the moment that the EU system for medical devices and IVD policy, market access and oversight is structurally underperforming and does not deliver on the promise of a future proof and state of the art regulatory system for medical devices and IVDs. This affects confidence and trust in the system, its stakeholders and the reliability of medical devices approved under the system. As a result of the continued fragmentation and under-resourcing of the system on both EU and Member State level structural problems such as timely notified body designation, pragmatic implementation of the MDR and IVDR, development of guidance and adaptation of the system to specific needs (e.g. orphan devices) are not addressed adequately except with repeated moving of transitional period deadlines in several amendments and corrigenda. BVMed and VDGH believe that more structural measures are needed to make the market access process more reliable and predictable and enable notified bodies to function more effectively. BVMed and VDGH further believe that the EU should step up international harmonisation efforts in the IMDRF and on bilateral basis. Finally, BVMed and VDGH believe that one of the core issues that makes Union devices policy underperform is the lack of central responsibility for the functioning and performance of the system, which could be centralised in a European level structure to be determined.

3 Supplement missing regulations

3.1 Fast Track Procedure for Innovations

3.1.1 Issue

The EU medical devices system has no dedicated pathway for innovative devices for which there is a specific need in society. Innovative devices comprise medical technology that, whether incremental or not, offers meaningful advantages over alternatives for users, patients, health institutions, reimbursement systems and/or society. Small and medium sized manufacturers, which comprise the majority of EU (in vitro diagnostic) medical device manufacturers, are the engine of innovation in medical technology, are treated the same as the largest manufacturers in terms of fees, timelines and cost of compliance.

As a result of this one-size-fits all approach, medical innovations that significantly improve outcomes and/or raise the standard of care take unnecessarily long to become available to patients.

3.1.2 Background

Where other jurisdictions have accelerated pathways to bring medical devices to the market (e.g. the FDA breakthrough devices program⁷, Japan's fast-track review process for pioneering devices), the regulations only provide for emergency authorization under article 59 MDR / 54 IVDR.

By contrast, the EU pharmaceutical law framework contains a number of accelerated or abbreviated pathways for medicinal products that are of major interest to public health.

Given the presence and success of abbreviated and accelerated pathways in other jurisdictions (e.g. the FDA breakthrough devices program) and the EU's intention to have the medical devices regulatory framework converge more with the medicinal products framework there is no objective reason why there would not be similar options for medical devices in the Union. Without an accelerated pathway for medical technology innovations in the EU, European patients with unmet medical needs, life-threatening or highly debilitating diseases have delayed options for treatment compared to other countries.

Abbreviated and/or accelerated procedures for innovations are available in several jurisdictions and in the EU under the medicinal products framework as these procedures serve public health goals. At Union level choices will need to be made who decides which devices and/or manufacturers are eligible for these procedures and who is responsible for this.

3.1.3 Solutions for discussion and opportunities

Solutions to this problem are readily available because several jurisdictions have developed successful local procedures. These procedures can be adopted for administration and application under the EU system. Procedures that can be envisaged are (in addition to orphan and niche devices discussed in sections 3.2 and 3.3 respectively) are:

- A fast-track procedure for devices that are innovative (e.g. by analogy to the FDA breakthrough devices program¹⁵);
- A conditional approval procedure for devices that address an unmet medical need (by analogy to medicines procedure). This could be available where the benefit of immediate availability of the device outweighs the risk inherent in the fact that additional data are still required. The additional data requirements could be set out in a PMCF/PMPF program to which the

¹⁵ <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>

manufacturer commits. This procedure should be distinguished from article 59 MDR / 54 IVDR, which provides for a pathway based on interests of public health or patient safety or health for devices that are not CE marked and do not need to be CE marked.

BVMed and VDPH see the following options to implement these procedures.

Option 1

Annex VII of the MDR / IVDR could be amended based on the delegation in article 36 (3) MDR / 32 (3) IVDR to include additional accelerated and/or abbreviated procedures. Member State competent authorities and/or the European accountable managing structure would have oversight over the application procedures based on articles 44 and 45 MDR / 40 and 41 IVDR.

Option 2

Alternatively, these procedures could be administrated by Member States. It would be possible to provide for a procedure under which either a Union level article 59 (3) MDR / 54 (3) IVDR derogation or a Union level article 97 MDR / 92 IVDR exemption¹⁶ is granted for the duration of the conformity assessment of the device.

Option 3

A third option would be to set up an EU level expert panel that provides an advice about eligibility for one of the fast track procedures mentioned above, after which the accountable managing structure takes a formal decision to award the procedure benefit. After that decision, the notified body concerned would apply the conformity assessment procedure.

In the US the services of the FDA decide if a device is eligible for breakthrough designation. In the Union it would need to be decided where the decision for eligibility is made. Since the designation of special status for public health purposes is a Member State decision, it would seem appropriate to attribute this decision to the Member States or to a specific EU level expert panel, because accelerated or abbreviated procedures serve a goal of public interest.

¹⁶ By analogy to the procedure in MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

3.2 Orphan Devices and diagnostics for rare diseases

3.2.1 Issue

Currently the MDR and IVDR are lacking a specific regulatory pathway for orphan devices such as paediatric devices or diagnostics for rare diseases (see under 3.3 below for niche products). Developing medical devices and diagnostics intended for small numbers of patients has little commercial incentive under normal market conditions, which is exacerbated by the conformity assessment pathways and regulatory burden for the lifetime of the device that adds to this cost. Manufacturers of orphan devices will focus their efforts on jurisdictions with orphan device and niche device regulations, where the orphan device reaches the market earlier, depriving Union patients of (early) access to these devices.

3.2.2 Background

The Commission and industry seem aligned on the need of a solution for orphan devices or diagnostics for rare diseases under the MDR and IVDR.¹⁷ The MDCG has stated in MDCG 2022-14 that sustainable solutions are needed in the mid- and long-term for orphan devices.¹⁸ The Commission has indicated to the Council that it considers that a solution for orphan devices should be tackled before the end of the extended transitional periods.¹⁹ Orphan medical devices are also addressed in the EU4HEALTH program 2022, targeting paediatric patients specifically.²⁰

Currently the Commission is gathering further evidence for the comprehensive evaluation of the MDR and IVDR due by May 2027 pursuant to Article 121 MDR / 111 IVDR.²¹ The findings of the Commission are that costs related to market access, in particular clinical evaluation and conformity assessment, often render the development of paediatric devices economically not interesting. Innovation for paediatric patients therefore lags behind the advances made in relation to non-orphan devices.

The Commission is currently considering an orphan devices policy of supporting non-profit organisations or consortia that provide a platform for academic bodies, scientific societies, developer of devices, in particular SMEs, and NGOs with a specific interest in innovative paediatric devices. The intention is to help foster and guide the development of orphan devices this way, for paediatric patients, in particular in areas

¹⁷ Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7

¹⁸ MDCG 2022-14, point 18

¹⁹ Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7

²⁰ See HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (<https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf>)

²¹ Information note from General Secretariat of Council, Brussels, 8 March 2023 6484/23, p. 7

of unmet medical needs in the EU4HEALTH programme.²² This takes inspiration from the Paediatric Device Consortia Grants Program of the US Food and Drugs Administration (FDA).²³ However, a number of other jurisdictions also have successful orphan device programs that may serve as source of inspiration, such as Brazil, China and Japan.

Arguably support of consortia or platforms that support development of orphan devices is not the same as adoption of a regulatory pathway for orphan devices like available for medicinal products. This seems to be missing in the Commission's actions under the EU4HEALTH framework. Jurisdictions like Brazil, China and Japan do have specific orphan devices pathways.

The MDCG, for its part, has indicated that it “will pursue work with a view to providing a definition for ‘orphan devices’ and suggesting specific guidance or other means of assistance for those products to be able to meet the legal requirements.”²⁴

3.2.3 Solutions for discussion and opportunities

BVMed and VDPH believe the MDCG's work on definition of orphan devices and diagnostics for rare diseases and means of assistance must be developed in close cooperation with all stakeholders in order to arrive at solutions that will be viable in the middle and long term and will have the intended effect.

An orphan designation for medical devices and diagnostics for rare diseases could be modelled on the orphan designation criteria for medicinal products of rarity, severity and unmet medical need for the device.²⁵ At EU level a much looser working definition is used: “medical devices, that benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition”²⁶. The definition can be incorporated in article 2 MDR / IVDR to ensure legal certainty. Alternatively, specific orphan medical conditions can be listed on a rolling basis at EU level by the accountable managing structure discussed in section 7.1 after SCHEER advice. They may also be included as an annex to the MDR or IVDR subject to amendment by the Commission after e.g. SCHEER advice based on delegation with a mechanism of

²² See HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (<https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf>)

²³ HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (<https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf>)

²⁴ MDCG 2022-14, point 18

²⁵ <https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview>

²⁶ HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (<https://health.ec.europa.eu/system/files/2022-11/wp2023annexen.pdf>)

periodic revision. Any devices with diagnosis or treatment of these conditions as intended purpose could qualify as orphan devices diagnostics for rare diseases.²⁷

Orphan status qualification could be done based on application of a definition alone, by a notified body, or by the accountable managing structure.

Appropriate elements of a devices orphan designation would be:

- Scientific advice for orphan devices and diagnostics for rare diseases analogous to protocol assistance for orphan medicinal products (to be implemented by means of a change to article 61 (2) MDR / 56 (2) IVDR);
- Fee reductions, grants (e.g. via EU4HEALTH program) or tax reduction²⁸; and
- Optional national incentives in Member States.

Conformity assessment of orphan medical devices or diagnostics for rare diseases could take place by means of a specifically described conformity assessment pathway set out in article 52 MDR / 48 IVDR and Annex IX, section 5, e.g. in a new section to be added this section. This conformity assessment pathway should be expedited, with shortened time periods for the different stages of the conformity assessment²⁹ and a fixed duration for the whole procedure as to ensure predictability of the process for the manufacturer in case of an orphan device.

3.3 Niche products

3.3.1 Issue

The current medical devices regulatory system does not provide for incentives to stimulate economically unsustainable niche (in vitro diagnostic) medical devices for specific conditions, where there may be unmet medical needs. Examples would be rare autoimmune diseases or allergies.

3.3.2 Background

Niche devices are devices that are designed to treat or diagnose a specific medical condition or used in a specific procedure and may be used in a specific medical field or be intended for a specific subset of patients. The main feature and at the same time problem of niche devices is that they have a limited market, and that their development and commercialisation are justified by the clinical need of a small but

²⁷ This model is used in China and Japan currently, see RegIntA report “Orphan Devices & Niche Products – Global Approaches”, June 2022, sections 2.3 and 2.4

²⁸ Certain jurisdictions (China and Japan for example) with orphan device programs provide tax reduction and government funding for R&D activities in the field of orphan medical devices, see RegIntA report “Orphan Devices & Niche Products – Global Approaches”, June 2022, sections 2.3 and 2.4

²⁹ Analogous to the HDE application for Humanitarian Use Devices (HUDs) in the US, which takes 75 days instead of 180 days, see RegIntA report “Orphan Devices & Niche Products – Global Approaches”, June 2022, section 2.6

identifiable group of patients, while not meeting requirements for an orphan device. Niche devices are often not profitable or may become not profitable if the investment in regulatory clearance and clinical data for the clearance process outweighs the expected profits.

They are distinguished from orphan devices by the fact that they are not intended for a specifically indicated orphan medical indication or do not meet the population size criteria for orphan device.

The small size of the target patient population makes it more difficult to conduct clinical or performance studies and generate sufficient clinical evidence to support regulatory approval for niche devices. Additionally, since the market for these devices is small, they face challenges in obtaining reimbursement from payers. This leads to a combination of relatively low turnover of the device combined with relatively high costs for clinical evidence and market approval.

3.3.3 Solutions for discussion and opportunities

Definition

The definition of the concept of niche (medical) devices can be fitted within the existing definition of medical devices. A definition can be provided in article 2 MDR or IVDR, or a solution can be chosen of listing categories of niche devices in an Annex to the MDR or IVDR (like with the Annex XVI devices – the Annex can be implemented by implementing act) or in an implementing act. Listing of categories of devices has the advantage of increased legal certainty.

A definition of niche device for inclusion in article 2 MDR / IVDR could consist of the following elements:

1. The device is intended for a specific patient group or specific medical application or diagnosis;
2. The device is commercially not viable if made available for the niche intended purpose alone; and
3. The device offers a significant clinical benefit or other advantage over CE marked alternatives with an intended purpose that does not include the niche patient group or niche application.

Conformity assessment pathway

Devices that meet the qualification criteria for a niche device are eligible for the niche devices conformity assessment pathway, which would be characterised by a number of elements. The manufacturer of the niche device can indicate in the conformity assessment application that the application concerns a niche device, which would be validated by the notified body against the qualification criteria for niche devices.

In order to make the regulatory pathway more predictable for niche medical devices article 61 (2) MDR should be amended as to include niche medical devices in its scope to obtain certainty at an early stage about the clinical development strategy for the niche device. There should be dedicated expert panels for niche devices. A similar solution can be considered for IVDs by adding a provision similar to article 61 (2) MDR into article 56 IVDR.

The conformity assessment pathway after scientific advice should be expedited, with shortened time periods for the different stages of the conformity assessment³⁰ and a fixed duration for the whole procedure as to ensure predictability of the process for the manufacturer in case of a niche device that is intended for an unmet medical need.³¹

Account should be taken of regulatory approvals elsewhere in the world, where available.

Gaps in clinical data (provided that the device has a demonstrable positive risk/benefit ratio) can be filled in by means of PMCF / PMPF.³²

Funding

Like orphan devices or diagnostics for rare diseases³³, niche devices should be able to profit from funding for the purpose of collecting clinical data, for example under the EU4HEALTH program, and be subject to tax reductions for R&D activities.

4 Measures to increase efficiency and implementation of principles of good administration

4.1 Introduction

The increased obligations for notified bodies and administrative formalities required under the MDR and IVDR have upset the historic partnership between manufacturers and notified bodies. This has led to several common challenges that are compounded by the inefficient notification designation process for notified bodies under the MDR and IVDR. Notified bodies take decisions with respect to the rights and obligations of private parties by granting, suspending, limiting and revoking certificates. BVMed and

³⁰ Analogous to the HDE application for Humanitarian Use Devices (HUDs) in the US, which takes 75 days instead of 180 days, see RegIntA report “Orphan Devices & Niche Products – Global Approaches”, June 2022, section 2.6

³¹ The criterion of unmet need could be copied from the orphan designation criteria for medicinal products: there must be no satisfactory method of diagnosis, prevention or treatment of the condition in the EU, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

³² This solution is adopted in Japan, see RegIntA report “Orphan Devices & Niche Products – Global Approaches”, June 2022, section 2.4

³³ See above under section 3.2.3

VDGH believe that consistent implementation of the principles of good administration in MDR and IVDR procedure is needed to ensure that the CE certification system under the MDR and IVDR continues to operate in a fair, transparent and predictable manner under administrative accountability.

4.2 Predictability of deadlines

4.2.1 Issue

At the moment there are no deadlines for conformity assessment procedure and quality system review, neither as regards (basically any of) the respective procedural steps, nor for the whole process. This makes it impossible for the manufacturers to plan their business reliably which defers investment in new and innovative devices. This insecurity and ensuing inability to plan affects SMEs the strongest.³⁴

4.2.2 Background

The lack of deadlines for taking market access decisions is prevalent in the EU medical devices framework. Notified bodies can define their own deadlines and these may differ between notified bodies.³⁵ Only in exceptional cases is there a specific harmonised procedural deadline (e.g. for the clinical evaluation consultation procedure under article 54 MDR or the scrutiny procedure under article 50 IVDR). As a result, manufacturers have no reliable way of knowing when the CE certificate for a device will be granted. Notified bodies can only provide rough estimates, which they may not be able to guarantee in practice as a result of the slowdown in the system and the bottleneck caused by the stunted implementation of the regulations. Not only are notified bodies confronted with an enormous spike in the number of conformity assessments, but also with a more extended review in the individual conformity assessments as a result of new requirements under the MDR and IVDR. This is exacerbated by the significantly increased bureaucracy and monitoring of notified bodies, which compound to such inefficiencies that this leads to a massive slowdown of the individual conformity assessments.

In addition, where manufacturers agree audit dates and time slots with notified bodies these are often moved in practice due to the capacity bottleneck affecting notified bodies themselves. In practice this leads to a situation where a notified body may use internal deadlines for planning purposes, but could not commit to a deadline

³⁴ Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 8; MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 7

³⁵ See Annex VII 4.5.1 MDR and IVDR requirement for notified body conformity assessment activities: “specify the rationale for fixing time limits for completion of conformity assessment activities”

for the conformity assessment process (even when this includes clock stops) like a medicinal products agency must in Europe.

It is a principle of good administrative practice when exercising government authority that citizens are treated equally and that a degree of certainty about the process is provided.³⁶ This is the standard in the medicinal products marketing authorization framework, which includes fixed durations for the whole procedure and fixed durations for the procedural steps.³⁷ Only clock stops during which the applicant has to supplement data or answer questions can add to the duration of the procedure.³⁸

4.2.3 Solutions for discussion and opportunities

The MDR and IVDR are already a blend of competent authority decisions and notified body decisions, which leads to a lack of predictability, resulting in business uncertainty and unknown availability of technologies for patient care.

There are several options for solutions to this issue. All options should preferably be combined with centralisation of policy and responsibility at EU level as discussed below in section 7.

Option 1 – defining procedures in Annex VII

Article 36 (3) MDR / 32 (3) IVDR provides for a specific legal basis for implementing acts for the uniform application of the requirements set out in Annex VII to the extent necessary to resolve issues of divergent interpretation and of practical application. An implementing measure defining specific procedures, fixing total duration of these specific procedures and providing specific procedural steps would fit in the scope of this attributed competence. In order to meet the principle of transparency the procedures' deadlines should be published by the notified body, in addition to the amendment of Annex VII. This option could be combined with Option 3 below (oversight of procedural deadlines).

The deadlines provided in Annex VII could be established with direct reference to the principles set out in the medicinal products framework:

- Fixed duration for the whole procedure, excluding clock stops;
- Fixed duration for procedural steps in relation to the procedure concerned, allowing for a transparent and reliable procedure;

³⁶ See article 41 Charter and European Parliament resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union (2012/2024(INL)) (<https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law>)

³⁷ <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step>

³⁸ <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step>

- Mechanism for change notifications that allows a manufacturer to proceed with the change if the notified body for example has not given notice of need to further investigate the change within two weeks after notification of the change by the manufacturer.

Article 56 (2) MDR / 51 (2) IVDR should be amended to include a rule that a certificate cannot expire as a result of the notified body not having scheduled audits timely or not completing conformity or QMS assessment before expiry date of the certificate. Good administration requires that citizens do not lose a right to market access just because the market access authority is unable to finish review in time before expiry of a license. The notified body should remain responsible for surveillance of the certificate if it cannot finish procedure in time before expiry of the certificate.

Option 2 – aligning all procedure legally with administrative procedural law in the notifying Member State

A quick win from a legal perspective would be to make notified body procedure subject to administrative law procedures in the notifying Member States. This may require a degree of definition of procedures in Annex VII for precision but would essentially be a blended model under which notified bodies are bound by administrative procedural law of the notifying Member State. This option relies on the theory that notified body decisions are exercise of state authority and should therefore be subject to the same administrative procedural controls as Member States licensing procedures. This would include standard review times for the whole procedure of license or steps in the procedure (such as a legal deadline for responding to a request for evaluation of a change as substantial or not). Where notified bodies do not meet deadlines, citizens have the normal administrative procedural remedies in the notifying Member State that they would have against the notifying Member States' administrative bodies.

Option 3 – oversight by specific auditing on meeting procedural deadlines

Option 1 could be combined with an option where the notifying Member State or another (EU) entity audits the notified body for meeting procedural deadlines and making service level measured in KPIs a criterion for redesignation of notified bodies. In addition, KPIs of notified bodies in this respect could be published periodically along with transparent pricing conformity assessment activities, allowing manufacturers to make an information decision as regards notified bodies.

4.3 Calculability of costs

4.3.1 Issue

The MDR and IVDR requires notified bodies to establish lists of their standard fees for the conformity assessment activities that they carry out and make those lists publicly available³⁹, as well as ‘operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of SMEs in relation to fees’.⁴⁰ While MDCG guidance has been provided with a template list of standard fees structure⁴¹ that has been in place for several months without transitional period, in practice notifying competent authorities do not seem to enforce against notified bodies that do not meet these requirements.

Because the notified body system is based on competition between (regulated) market driven services providers, the theory is that notified bodies will compete on price and quality of service. In practice neither happens. Moreover, notified bodies can (and do) change their prices often as there are no MDR or IVDR controls to prevent this.

Furthermore, there is a considerable proliferation of fees and fee structures among the dozens of notified bodies: each notified body uses its own rate structure and generally does not publish it at all or at an easily accessible location on the internet, which makes it impossible for companies to meaningfully compare notified bodies regarding prices of specific actions and overall conformity assessment costs. In addition, because notified bodies charge for their services by the hour and may added additional procedure related costs the total costs of conformity assessment cannot realistically be planned by an applicant.

In addition, notified bodies do not differentiate in prices between bigger and small customers, leading to a situation where SMEs have difficulties affording conformity assessment in the Union and cannot afford special fast track assessment pathways offered by notified bodies such as expedited review at a higher service level (faster and/or more reliable planning) at considerably higher costs than normal conformity assessment service level, leading to unequal treatment of applicants based on available budget.

4.3.2 Background

The proliferation of fees structures even at a single agency has been marked as unwanted with regard to medicinal products. By way of example EMA fees structure

³⁹ Article 50 MDR / 46 IVDR

⁴⁰ Annex VII, 1.2.8 MDR / IVDR

⁴¹ MDCG 2023-2

revision shows what a responsible public policy should look like, and how a transparent and equitable fee structure can be created for public law exercise of powers, yet based on cost-reflectiveness and taking into account vital public policy objectives such as predictability, administrative burden, position of SMEs, impact on research and innovation and functioning of the internal market.⁴²

The guidance provided in MDCG 2023-2⁴³ is a first small but still ineffective step towards a degree of transparency of rates. It does not fix the problem because notified bodies can still decide what activities are invoiced on what basis (flat, hourly or daily) and provide a range for conformity assessment activities that the notified body may divert from where it thinks that is justified⁴⁴ and can diverge at will, relying on “factors not considered in a list of standard fees”.⁴⁵ At present BVMed and VDPH are unaware of any notified bodies that actually use the model standard fee list provided in MDCG 2023-2.

MDCG 2023-2 requires notified bodies to provide a minimum-maximum range per separate activity, which can lead to a very wide bandwidth in total for the added items comprising the conformity assessment procedure. Currently, the only requirement in non-binding guidance is that “in case of substantial difference between the quotation and the final fee charged, notified bodies should notify manufacturers about the discrepancy and duly justify this adjustment.”⁴⁶

Market access of innovative medical devices is a matter of public health policy. BVMed and VDPH are concerned to see that especially for innovative devices the MDR and IVDR contain more complex and time consuming procedures that increase costs, such as the clinical evaluation consultation procedure for class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, the scrutiny procedure for class D IVDs and the companion diagnostics procedure.

A significant proportion of innovations in medical devices comes from SMEs. There is an accepted definition of SMEs in the Union market that is used also for SME benefits

⁴² Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final, sub 3 Impact Assessment (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0721>)

⁴³ MDCG 2023-2 List of standard fees

⁴⁴ MDCG 2023-2, p. 3: “The quotation and fees actually charged, including individual items for an individual project, can be different for individual devices due to factors not considered in a list of standard fees. In case of substantial difference between the quotation and the final fee charged, notified bodies should notify manufacturers about the discrepancy and duly justify this adjustment.”

⁴⁵ MDCG 2023-2, p. 3

⁴⁶ MDCG 2023-2, p. 3

under the medicinal products system that can be followed for the MDR and IVDR.⁴⁷ The market access system for medical devices should therefore not have unduly high financial barriers for SMEs as it currently has. Currently the only requirement is that the notified body should have ‘fair’ rates and should also indicate how the interests of SMEs are taken into account.⁴⁸ In medicinal products market access at the EMA provision has been made for SMEs in order to ensure that the central marketing authorization pathway is affordable for SMEs as well. Oversight of compliance of rates with the criteria in Annex VII, 1.2.8. (consistent, fair and reasonable) could be performed possibly by the accountable managing structure discussed in section 7.1 below.

4.3.3 Solutions for discussion and opportunities

EU harmonization of fees and fee structures would allow for transparency and possibility to compare between notified bodies and to arrive at fees that are indeed fair and reasonable as required under the MDR and IVDR.⁴⁹ The Commission could set fee bandwidths or fees for a specific conformity assessment activity or procedure. This way it can be ensured that the fees reflect the underlying costs of the notified bodies better. BVMed and VDPH believe that rate structures that allow for fast tracking, more reliable planning or other increased service levels at notified bodies in exchange for increased fees are not fair and reasonable as the effect is unequal treatment of applicants based on their ability to pay fees alone.

By analogy to the Commission’s proposal to change the EMA’s fee system, fixed fees or fee bandwidths for notified bodies set by the Commission by means of delegated⁵⁰ or implementing acts under the MDR and IVDR could be combined with a cost monitoring mechanism and a degree of flexibility to adjust fees to significant changes in costs.⁵¹ It should under, all circumstances, be a principle that costs for the market access system can be, reliably recouped, and that for the scarcity of capacity should not be a justification for higher fees. Like with the revision of the fee structure for the

⁴⁷ Commission Recommendation 2003/361/EC

⁴⁸ MDCG 2023-2, p. 3

⁴⁹ Annex VII, 1.2.8.

⁵⁰ The EMA fees structure revision regulation uses delegated acts for the Commission competence, see Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final

⁵¹ <https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/european-medicines-agencys-ema-fee-system-impact-assessment-and-commission-proposalen>

EMA it could be considered to include fees for minor post-authorisation procedures (e.g. such as evaluating changes to devices) in the annual surveillance fees.⁵²

In addition, SME benefits could be considered in specific cases given the increased time and cost of procedure under the MDR and IVDR. SME discounts are a normal phenomenon in e.g. the medicinal products framework, where SME get very substantial discounts for market access procedure fees at the EMA of up to 100% for certain procedures.⁵³ By analogy the MDR and IVDR could be amended for a central SME office at EU level that assigns SME status to a manufacturer and entitles the manufacturer to SME benefits awarded under the MDR and IVDR (see also in section 7.1). The SME office provide guidance for SMEs and certain public subsidies ,can also monitor that notified bodies and notifying competent authorities (when auditing their notified bodies) duly take SME interests into account.

4.4 Access to the system

4.4.1 Issue

The notified body certification system under the MDR and IVDR operates based on the principle of a regulated market. This leads to the situation that manufacturers experience the negative effects of markets and scarcity in the form of high fees for certification. At the same time manufacturers can legally only place products on the market by relying on a process that is not controlled by principles of good administration, such as equal access to certification and transparent and predictable procedures. In practice some manufacturers are refused access to notified bodies and are unable to obtain regulatory approval for their devices. This is especially the case for small and medium sized undertakings and first-time applicants.

4.4.2 Background

The MDR and IVDR rely heavily on commercial third party involvement in conformity assessment due to the policy choice to organise conformity assessment of medical devices this way. The commercial third parties involved are the notified bodies, while competent authorities of Member States generally limit their role to market surveillance. Notified bodies, as the commercial undertakings that they are, prefer to concentrate on customers with a relatively large amount of predictable work, as this

⁵² See Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council, COM/2022/721 final

⁵³ <https://www.ema.europa.eu/en/human-regulatory/overview/support-smes/financial-advantages-sme-status>

leads to economies of scale for the notified body, resulting in an improved profit margin. However, this also provides notified bodies with a potential incentive to refuse services to smaller and medium sized manufacturers that take up more time relative to possible turnover. The MDR and IVDR do not provide for a duty of notified bodies to accept customers or to not refuse them on arbitrary grounds, only that the notified body must have an onboarding procedure.⁵⁴ Accepting customers on a non-discriminatory basis is currently not a requirement under Annex VII MDR / IVDR.

The Commission has stated publicly that small manufacturers' access to notified bodies is a structural issue in the medical devices framework that needs to be tackled in the short term because it has a negative impact on patient safety, public health and medical innovation.⁵⁵

The MDCG has published and suggested limited non-legislative measures by means of MDCG 2022-14 that features 19 points intended to improve the functioning of notified bodies and intends to free up capacity at notified bodies. Also the extra time afforded under the recent MDR and IVDR amendments for notified bodies to finalise conformity assessment in the period 26 May 2024 to 31 December 2027 or 2028 under the MDR and up to 26 May 2027 under the IVDR respectively is intended to free up capacity at notified bodies. However, these measures comprise funding of actions that are not expected to achieve any serious difference in the short term because they concern no concrete solutions other than 'a call for proposing solutions to facilitate matching the demand of market operators with the availability of notified bodies.'⁵⁶ The Commission has already indicated that the current measures set out in MDCG 2022-14⁵⁷ are not enough.⁵⁸

Notifying Member States policy for monitoring notified bodies on whether they refuse access to certification services on non-discriminatory or non-arbitrary grounds is not harmonised. The Member States that do monitor do not publish the result of this monitoring and the consequences for their policy. There is no effective formal pathway to complain to a notifying Member State about a notified body refusing service.

Especially SMEs and first-time applicants are often unable to find notified bodies willing to onboard them, which is an indication that the market access system for medical devices is not functioning well because its access mechanism discriminates

⁵⁴ Annex VII, 4.3 MDR / IVDR

⁵⁵ Commission Information note to the Council 6484/23 of 8 March 2023, p. 6

⁵⁶ Annex 2 EU4Health work programme 2022, Commission Implementing Decision C(2022) 5436 final of 25.7.2022, action HS-g-22-19. p. 76

⁵⁷ MDCG 2022-14, under 12 -13

⁵⁸ Commission Information note to the Council 6484/23 of 8 March 2023, p. 7

between applicants based on their size and incumbency in the system. This is contrary to the principle of good administration.

4.4.3 Solutions for discussion and opportunities

The principles of good administration enshrined in article 41 of the EU Charter of Human Rights should be implemented for the medical device market access system, one of which is that persons relying on the approval system are treated equally and must be able to appeal a decision of a notified body, just as would be possible when market access decisions are taken by government body.

Several options can be considered:

- Annex VII is amended to add a prohibition against discrimination and non-arbitrary onboarding of customers in the QMS of notified bodies, subject to surveillance in the notifying member state;
- Onboarding procedures of notified bodies must provide explicitly how the notified body will ensure non-discriminatory access to service, taking the interests of notified bodies into account. This policy and its application should be audited and monitored by the notifying Member State. The MDCG, the European level structure or an oversight body could develop harmonized elements for the procedure as this would be in scope of explicitly attributed competence under articles 105 (b)⁵⁹, (g)⁶⁰ and (h)⁶¹ MDR / 99 (b), (g) and (h) IVDR;
- Possibility to file a complaint at the notifying Member State or the European level structure directly for refusal of service if no appeal is possible against notified body decisions to refuse service. The Member State or the European level structure will handle the complaint and a responsible authority (for example the European level structure) will publish periodically which notified bodies have refused service on what grounds;
- Refusal of service by a notified body should constitute an administrative decision subject to appeal in the notifying Member State. Good administrative practice dictates that a decision of Member State to indirectly refuse to take a decision on market access of a medical device must be subject to appeal and scrutiny by a court by analogy to decisions by government agencies that refuse an application;

⁵⁹ “to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article [49 MDR/ 45 IVDR]”

⁶⁰ “to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;”

⁶¹ “to contribute to harmonised administrative practice with regard to devices in the Member States”

- A central load balancing mechanism administrated via the European level structure, or requirement for Member States to balance between their notified bodies, could be contemplated. Notified bodies from all Union Member States could be obliged to continuously indicate capacity to take on new customers, which could be consolidated on Union level, leading to a Union scoreboard showing what notified bodies have capacity. A call for a mechanism like this has already been made under the EU4Health work programme 2022.⁶²

4.5 Transparency of notified body procedure and surveillance

4.5.1 Issue

There is no effective control over or transparency with regard to the functioning of notified bodies, neither on a national level nor on an EU level. Annex VII MDR / IVDR requires that notified bodies should have internal procedures for customer facing activities⁶³ but does not require that these are transparent to the stakeholders. It is not transparent what directives notified bodies receive from their notifying competent authorities or the Joint Assessment Teams that can lead to national divergences in notified body practice, such as with respect to possibilities for remote audit. Notified bodies are not allowed to have a discussion with their customer regarding their procedures as this is deemed prohibited consultancy. Notified bodies are not EU administration as such, nor are they seen by Member States as part of their administrative organs. As such, the notified bodies escape the level of transparency and accountability that would normally be expected from government agencies that exercise state decision making authority.

4.5.2 Background

Historically Member States (re-)designate their own notified bodies according to rather loosely defined criteria in the notified body designation handbook. Under the MDR and IVDR this has become more of a cooperative exercise involving other Member States and the Commission in the Joint Assessment Team (JAT).⁶⁴ The MDCCG Notified Body Oversight Group (NBO) oversees issues relating to notified bodies and the application of conformity assessment procedures with the aim of a consistent application of requirements and procedures. However, this subgroup is closed to

⁶² Annex 2 EU4Health work programme 2022, Commission Implementing Decision C(2022) 5436 final of 25.7.2022, action HS-g-22-19.03, p. 76.

⁶³ See e.g. Annex VII, 4.8 which states that notified bodies should have procedures for the issuance, suspension and withdrawal of certificates without imposing any degree of transparency with respect to the exercise of these delegated government powers.

⁶⁴ Article 39 (3) MDR / 35 (3) IVDR

stakeholders, while all of the other MDCG Working Groups except PMS are open to stakeholder participation.

Transparency is further hampered because notified bodies are prohibited from offering procedural assistance to market actors, which severely limits transparency, predictability and efficiency of the conformity assessment process. Current measures of the MDCG and the Commission are only oriented to increasing notified body capacity but not to increasing notified body quality and customer-friendliness. MDCG 2022-14 only refers to the MDCG wish expressed that “notified bodies should **rationalise and streamline internal administrative procedures**, and ensure that proper conformity assessments are carried out in a timely and efficient manner in accordance with the Regulations.”⁶⁵ The MDCG encourages notified bodies in the same guidance document “to organise **structured dialogues** before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body”.⁶⁶ Structured dialogues will greatly improve the quality of applications for conformity assessment, as manufacturers will have a better picture of what the notified body would like to see in an application. Pre-submission meetings for precisely this purpose are a normal procedural phenomenon for medicines marketing authorisation applications, intended to discuss details regarding the procedure with the persons responsible at the government body. However, the MDCG does not provide any transparent detail on what a structured dialogue would look like for (in vitro diagnostic) medical devices and refer the further implementation to the MDCG and its subgroup the NBO (one of the two MDCG subgroups that does not admit stakeholders). Transparency about work processes and internal procedures at notified bodies is an important step for procedural accountability of notified bodies if these procedures concern establishing or affecting the rights of citizens, such as issuing, restricting, suspending or revoking certificates. Precisely for this reason government agencies are required to be transparent about their work processes, so they may be held accountable for their correct application of these processes. Article 41 of the Charter requires that as a function of good administration the principle of consistency and legitimate expectations public administration shall be consistent in its own behaviour and shall follow its normal administrative practice, which shall be made public. This is precisely where accountability of notified bodies is lacking because there is no requirement to make their administrative practices public. Even

⁶⁵ MDCG 2022-14, point 6

⁶⁶ MDCG 2022-14, point 15

the MDCG does not stimulate this in MDCG 2022-14, point 6, where it merely promotes harmonisation of internal administrative procedures of notified bodies.

4.5.3 Solutions for discussion and opportunities

As a first step, mandatory publication of and transparency about internal administrative practices of notified bodies as required by EU guaranteed fundamental rights of citizens (good administration under article 41 of the Charter) would serve to establish baseline procedural accountability for notified bodies. This way it becomes possible for stakeholders to verify if notified bodies adhere to their own internal procedures that they are legally obliged to have. This is also required for the structural dialogue process to lead to reliable enhancement of efficiency and predictability of the conformity assessment process. A flanking measure for harmonisation of notified body procedure would be introduction of a harmonised conformity assessment application submission framework like the eCTD (electronic common technical document) for medicinal products.⁶⁷ A good substantive basis for this has been laid by Team-NB notified bodies with the Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of the MDR⁶⁸ and the IVDR⁶⁹. An electronic Common Technical Documentation for Medical Devices (eCTDMD) could be developed as a harmonised technical solution to implementing Annex II and III electronically. This could comprise the submission of PDF documents, stored in the eCTDMD directory structure, accessed through the XML backbone and with the files integrity guaranteed by a checksum. Such dossiers should be able to be submitted and managed by means of machine-to-machine (M2M) communication.

The MDCG subgroup NBO, in cooperation with notified bodies, could develop a Code of Notified Body procedure in addition to the requirements in Annex VII to 'have a procedure'. This Code should be developed in cooperation with all stakeholders and should include details on the structured dialogues mentioned in MDCG 2022-14.

Alternatively, Annex VII could be amended to provide procedural detail for procedures that may lead to any individual measure which would affect no rights or obligations of a manufacturer adversely to be taken, including details on the structured dialogues mentioned in MDCG 2022-14. This requires that the NBO working group at the MDCG is opened up to stakeholder participation. Stakeholder participation will also enable the Member State members of the MDCG and the Commission to be better informed about performance of notified body guidance

⁶⁷ <https://esubmission.ema.europa.eu/ectd/index.html>

⁶⁸ <https://www.team-nb.org/wp-content/uploads/2022/10/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V1-20221005.pdf>

⁶⁹ While no public version of this document has been published by Team-NB a draft for stakeholder consultation has been circulated and a final version is expected to be published soon.

issued by the MDCG. Also, stakeholder participation allows for a better process of developing of guidance by means of impact assessment involving stakeholders. The Commission itself states that impact assessments are to be carried out on initiatives expected to have significant economic, social or environmental impacts.⁷⁰ Impact assessments form a key part of the Commission's Better Regulation agenda, which seeks to design and evaluate EU policies and laws so that they achieve their objectives in the most efficient and effective way.⁷¹ Given the impact of MDCG guidance documents for the EU regulatory system as function of EU policy to be followed such impact assessments should be performed for MDCG guidance in the field of notified bodies and even more generally.

There should be a clear contact point in the notifying Member State where complaints about the notified body can be lodged by economic operators that Member States must follow-up on and provide the economic operator with feedback about their handling of the complaint, in keeping with article 41 of the Charter (good administration). At present the MDR / IVDR only allows for challenge of the competence of the notified body as such.⁷² Alternatively stakeholders should have access to the European Ombudsman.

The Member State's audit of notified body performance in accordance with article 45 (1) MDR / 41 (1) IVDR should also include a review of how the notified body has treated customers procedurally and of procedurally defined KPIs, e.g. the amount of appeals lodged against notified body decisions, the grounds for complaints and the statistics on the notified body's decisions on these complaints. These KPIs can be published on the Commission website in a KPI dashboard overview, so customers can compare notified bodies, and they can serve as a basis for audit by designated Member States. For example, a notified body that has relatively high complaint rejection rate compared to others on certain specific appeal grounds may be acting arbitrarily or not be impartial.

There should be further going harmonisation and transparency of national and EU level controls on notified bodies performance. Harmonisation currently only covers the designation criteria with no transparency on MDCG and Member States' controls over notified bodies.

⁷⁰ <https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/impact-assessmentsen>

⁷¹ <https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulationen>

⁷² Article 47 MDR / 42 IVDR

4.6 Substantial Change

4.6.1 Issue

The current mechanism of approval of each substantial change before it can be implemented leads to an undue regulatory burden, unnecessary costs and to delays in changes (which may include innovations or smaller iterations to improve the safety or performance of a device). There is a need for a recalibration with regard to changes that the manufacturer can perform himself within the quality system and changes that need notified body assessment. Also, there is a need for a reliable and predictable procedure for evaluation of changes that must be approved by the notified body.

4.6.2 Background

Each individual substantial change to a device must be approved by the notified body before the change can be implemented, and the manufacturer must notify each change for the notified body to determine if it is substantial or not. However, there is no duration for the change approval procedure and there is no defined concept of substantial change in the MDR or IVDR. There is an old NBOG guidance document⁷³ that defines substantial changes, but this is not appropriate anymore for the MDR or IVDR. Reportable changes are not described logically and consistently in the MDR and IVDR.

The 'old' substantial change thinking under the Directives is Annex X thinking, see Annex X 5.1 and 5.2 MDR / IVDR, which does not return in Annex IX, see Annex IX 2.4 MDR and IVDR. Which is focused on evaluation of every change to a device type. Under Annex IX the manufacturer should be able to do a lot more himself in terms of changes, because this is the rationale of a full QMS assessment: that the manufacturer has been certified to be able to manufacture the devices in scope of the product certificate coupled to the QMS certificate. The intention behind Annex IX is to give the manufacturer considerable room within the guardrails of the scope of the technical documentation and QMS evaluated.⁷⁴

4.6.3 Solutions for discussion and opportunities

A much clearer definition of substantial change is required. A definition could be included in article 2 of the MDR / IVDR, which could be elaborated in Annex IX and/or (further) elaborated in an MDCG guidance document. This will also allow solving of the continuing confusion between the concepts of substantial change and significant

⁷³ NBOG 2014-3 Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

⁷⁴ See also Module D as set out in Blue Guide p. 143 (Annex 4) and Decision 768/2008.

change in the meaning of article 120 (3c) MDR and 110 (3) IVDR regarding legacy devices now that MDR legacy devices will have certificates with validity of up to 31 December 2028 and IVDR legacy devices up to 26 May 2027.

It should be possible to group notifications of potential substantial changes and transmit them to the notified body on a periodical basis. Grouping of variations for medicines is for example possible; the Variation Regulation contains a specific regime for variation grouping that allows grouping the same variations concerning for example several products of the same marketing authorisation holder or several variations affecting the same medicinal product.⁷⁵

There should be a procedure with time limits for the notified body to review submitted changes. This procedure should contain a mechanism that may or may not be only applicable to certain categories of changes) that allows the manufacturer to proceed with the change as non-substantial if the notified body does not indicate that further review is needed within a fixed period (e.g. two weeks) of notification.

Review of changes should be subject to a standard fixed procedure fee by analogy to variations under the medicinal products framework.⁷⁶

4.7 System-inherent possibility to complain

4.7.1 Appeal at notified bodies and other parties involved in the application of the regulatory system

The MDR and IVDR do not provide for a standardised pathway for complaints at parties involved in application of the regulatory system under the MDR / IVDR that meets the basic requirements of good administration as out in article 41 Charter.

4.7.2 Background

Various actors are involved in the application of the MDR and IVDR: notified bodies, expert panels, Member State authorities attributed with competence in the field of clinical investigation application assessments and competent authorities. In the case of Member States authorities appeal against first instance decisions is provided for under national law. In the case of expert panels or consultation of medicines authorities a scientific opinion is delivered that the notified body must give due consideration to, but the expert panel or medicines authority does not take a

⁷⁵ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/variations/grouping-variations-questions-answers>

⁷⁶ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, OJ 2008 L334/7

decision itself.⁷⁷ This means that as of the actors involved in application of the MDR and IVDR only notified bodies take decisions with legal effect as regards the rights of citizens, but without requirements of good administration applying to them. The principles of good administration in relation to the application of the MDR and IVDR only apply to competent authorities.⁷⁸

Annex VII MDR / IVDR obliges notified bodies to have a procedure for complaints in their quality system, but this procedure is not standardised or described in any transparent detail.⁷⁹ The procedural guarantees of good administrative practice are not set out for this procedure. It is not possible for manufacturers to file a complaint in a standardised way against a decision of the notified body that comes down to exercise of delegated Member State competence (issuing, suspending, restricting or revoking CE certificates).

However, good administrative practice enshrined in article 41 of the Charter provides that decisions taken by public bodies exercising Member State authority should be subject to a number of harmonised principles of good administration⁸⁰:

- Principle of non-discrimination and equal treatment (currently not addressed in Annex VII MDR / IVDR);
- Principle of proportionality (currently not addressed in Annex VII MDR / IVDR);
- Principle of impartiality (currently addressed in Annex VII MDR / IVDR to a limited extent);
- Principle of consistency and legitimate expectations (currently not addressed in Annex VII MDR / IVDR); and
- Principle of transparency (currently not addressed in Annex VII MDR / IVDR).

Notified body internal procedure to arrive at binding decisions regarding conformity assessment and regarding the restriction, revocation and suspension of certificates should be built on these principles. Internal appeals procedures should moreover be in line with article 47 Charter (right to a fair trial) which dictates procedural requirements for internal appeals procedures.

It is a legal hiatus that notified body decisions based on exercise of delegated state authority (grant, suspension, restriction and revocation of certificates) are not subject to legal review, as is for example the case with medicinal products marketing authorisations (see below under 4.8 regarding legal review), and moreover contrary

⁷⁷ Annex IX, 5.1 (g) MDR / Annex IX, 5.2 (e) IVDR

⁷⁸ Article 99 MDR / 94 IVDR

⁷⁹ There is only the ISO 17021 standard by way of standardisation, which gives very high level direction but no concrete procedures implementing good administrative practices.

⁸⁰ <https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law>

to article 47 of the Charter and article 6 (1) of the European Convention on Human Rights (right to a fair trial).

4.7.3 Solutions for discussion and opportunities

Annex VII of the MDR and IVDR could be amended to define a precisely prescribed pathway for a complaint procedure against a decision that is modelled on the principles of good administration as set out in European Parliament resolution of 15 January 2013 with recommendations to the Commission on a Law of Administrative Procedure of the European Union (2012/2024(INL))⁸¹, which defines a complete internal appeal pathway for a conformity assessment body (CAB)/notified body that conforms to the principles of good administration laid down in article 41 Charter, such as setting of procedural timelines.

Article 53 MDR / 49 IVDR could be amended with a reference to an internal appeals procedure detailed in Annex VII and a legal review pathway in a Member State court in conformity with Article 47 Charter, see below under 4.8 for more details.

For the purposes of transparency and non-discrimination EU level procedural templates should be developed, which could form part of Annex VII.

4.8 Legal review of decisions

4.8.1 Issue

In practice it is impossible for manufacturers to challenge a decision by a notified body regarding the certification status of their devices in an independent court or to engage a notifying Member State in case of disagreement between notified body and manufacturer other than in classification disputes (for which the MDR provides a specific escalation procedure in article 51 (2) MDR and 48 (2) IVDR). There is no viable pathway for a challenge other than a claim in contract in civil court based on non-performance under the certification agreement. Any legal recourse taken by the manufacturer generally leads to the notified body ceasing conformity assessment activity for the manufacturer. Accordingly, there is no effective mechanism of administrative accountability for the notified body's decisions that affect the rights and obligations of citizens.

4.8.2 Background

Notified bodies take decisions with delegated state authority where they decide about rights and obligations of citizens by means of grant, restriction, suspension or

⁸¹ <https://fra.europa.eu/en/eu-charter/article/41-right-good-administration#eu-law>

withdrawal of CE certificates. Yet, the relationship between a notified body and the manufacturer is based on a civil law contract that does not provide for any viable ways to challenge a decision regarding certification status, as this would need to be cast legally as non-performance under the certification agreement.

Where a government body would need to follow principles of good administration, notified bodies are merely required to have a procedure⁸² and to operate on a basis of impartiality⁸³, without effective controls or appeal possibilities. The only remedy that manufacturer have is to take contract or tort law legal action based on the certification agreement, which does not provide for effective legal recourse. Where a notified body exercises state authority, EU law and the European Treaty for Human Rights (ECHR) requires that an effective procedure for legal recourse is available.⁸⁴ Where government authority is exercised this must take place based on the principles of good administration, which are currently not a requirement for exercise of government authority by notified bodies. This is a requirement for competent authorities under the MDR and IVDR⁸⁵ but inexplicably this is not the case for notified bodies, even if they also exercise state authority that is delegated to them.

In case of a legal challenge based on the certification agreement or in tort notified bodies have QMS procedures that cause them to put a hold on any other activity for the manufacturer, which makes it impossible for the manufacturer at the moment to have notified body activity reviewed by a court. Any legal action triggers a complete halt of activities for manufacturer products under evaluation, which effectively prevents manufacturer access to a fair trial regarding the exercise of government authority, which is therefore contrary to article 47 Charter and Article 6 (1) ECHR. An entity attributed with state authority cannot refuse service as a deterrent to being held accountable by means of legal review, and this does not happen with market access procedures administrated by government agencies, with medicines as a case in point.

4.8.3 Solutions for discussion and opportunities

The problems with lack of good administration and access to a fair trial can be remedied by either moving (part of) notified body exercise of state authority to a government body that takes the market access decision (option 2) or subjecting notified body exercise of state authority to legal review procedures in Member States

⁸² See for example Annex VII, 4.8 in relation to notified body decision relating to issuance, restriction, suspension or revocation of the CE certificate.

⁸³ Annex VII, section 1.2.2 and 1.2.3

⁸⁴ Article 6 (1) ECHR and article 47 of the EU Charter on Human Rights; ECHR Van Benthem case (23 October 1985, case 1/1984/73/111 (<https://nl.wikipedia.org/wiki/ArrestBenthem>))

⁸⁵ See article 99 MDR / 94 IVDR on good administrative practice

or at the General Court in Luxembourg that would apply to similar decisions, e.g. like marketing authorisation decisions for medicines (option 1).

Option 1

Notified bodies can be made subject to the requirements of good administrative procedure by including notified bodies in the scope of article 99 MDR / 94 IVDR for notified body decisions with effect on the scope or validity of the certificate (restriction of scope, suspension and revocation). By analogy to article 54 (2) MDR / 47 (2) IVDR regarding classification disputes between the manufacturer and a notified body a general right to appeal a notified body decision to a competent authority in a Member State or a court in a Member State could be provided for, thus ensuring implementation of the fundamental principles of good administration and a fair trial as enshrined in the Charter and the ECHR. This would require significantly more in terms of central oversight to ensure uniform application of legal review of notified body decisions and makes stakeholder participation extra important as an instrument to spot national differences and calibrate the overall system.

Option 2

To have the final market access decision taken by a government structure for market access to the whole internal market the model of the EMA and Commission can be copied from Regulation 726/2004 under which the EMA provides an advice and the Commission takes the decision.⁸⁶ By analogy the notified body could provide a certification advice to either the notifying Member State or a central EU structure or the Commission like it currently provides to its internal certification board, based on which the government structure issues a decision subject to legal review in the Member State (in case of Member State competent authority) or at the General Court (in case of an EU level government structure /Commission). This should apply to all notified body decisions with effect on the scope or validity of the certificate. This option would allow for the most harmonisation of notified body decisions through the consolidation of all currently existing certification bodies while keeping the system of conformity assessment by notified bodies intact. This option has been contemplated as policy option 1G in the Impact Assessment for the MDR and IVDR.⁸⁷ For this option to not delay approval the period between submission of certification advice and certification decision should be as short as possible and the procedure

⁸⁶ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004, L136/1

⁸⁷ Impact Assessment, Part I (SWD(2012) 274 final), p. 30

should be limited to specific categories of high risk devices.⁸⁸ This way an proportionate balance can be struck between a longer procedure but more harmonisation and legal certainty.

4.9 Overlapping EU legislation and national legislation

4.9.1 Issue

Overlapping EU regulations require manufacturers to obtain CE marking or approval under multiple different regulations, leading to unnecessary costs, regulatory burden and time to approval.

The slow implementation of MDR and IVDR lead Member States to impose national controls to compensate for lacking EU implementation, notably with respect to registration of economic operators and devices. This has caused additional formalities and overlapping registration requirements where the MDR and IVDR were supposed to eliminate these.

4.9.2 Background

Devices in scope of the MDR and IVDR can also be in scope of many other regulations, such as the Radio Equipment Directive, the AI Regulation and various EU legal instruments in scope of the EU Green Deal. This overlap leads to multiple product regulations applying to a single product. These multiple regulations use different definitions for often the same concepts, which makes them impossible to apply to a single product.⁸⁹

There is not a single methodology for dealing with these overlaps. As can be seen in article 1 MDR / IVDR, there are a large number of overlaps with other legislation that are dealt with in a number of different ways:

1. MDR / IVDR is *lex specialis* – other regulation does not apply (EMC Directive⁹⁰);
2. MDR / IVDR is *lex specialis* and risks not sufficiently addressed under MDR / IVDR but addressed in other regulation are taken into account for MDR / IVDR conformity assessment (Machinery Directive⁹¹); and

⁸⁸ Impact Assessment, Part I (SWD(2012) 274 final), p. 44

⁸⁹ An example is the AI Act, which defines concepts defined in the MDR and IVDR differently than under the MDR and IVDR yet requires that in case of overlap the manufacturer uses overlapping technical documentation.

⁹⁰ See article 1 (11) MDR / 1 (5) IVDR

⁹¹ See article 1 (12) MDR / 1 (6) IVDR

3. Overlap is not managed at all (for example: Radio Equipment Directive⁹², draft AI regulation⁹³, EcoDesign Directive⁹⁴, REACH Regulation⁹⁵, CLP Regulation⁹⁶, Packaging and Waste Directive⁹⁷, Batteries Directive⁹⁸ and POP Regulation⁹⁹).

This makes it complex and costly for manufacturers to comply with regulation. Especially the third group of regulation often dovetails with the MDR / IVDR in very unproductive ways. A case in point is the draft AI Regulation that requires CE marking under both the MDR/IVDR and the AI Regulation by notified bodies that must be designated under the AI Regulation or under the MDR/IVDR (or both), doubling the certification burden for a device with AI. It furthermore contemplates the use of overlapping technical documentation for MDR / IVDR and AI Regulation compliance but uses different definitions for the same basic CE marking related concepts, making such overlapping technical documentation technically impossible.¹⁰⁰

The slow implementation of aspects of the MDR and IVDR, notably as regards Eudamed, has led Member States to fill in the gaps with their own national legislation, even if the Commission has requested Member States specifically not to do so. As a result some Member States have introduced new national databases, mandatory use of Eudamed or other requirements, leading to additional costs and time needed for manufacturers to comply.

⁹² Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, OJ 2014 L153/62

⁹³ Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021) 206 final

⁹⁴ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (Text with EEA relevance) OJ 2009 L285/10

⁹⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L396/1

⁹⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ 2008 L353/1

⁹⁷ Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ 1994 OJ L365/10

⁹⁸ Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, OJ 2006 L 266/1

⁹⁹ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ 2019 L169/45

¹⁰⁰ <https://www.government.nl/documents/publications/2022/05/25/legal-analysis-european-legislative-proposal-draft-ai-act-and-mdr-ivdr>

4.9.3 Solutions for discussion and opportunities

The MDR and IVDR would benefit from one clear overlap rule that applies for all overlapping regulation and leads to the least administrative burden for the manufacturer, while at the same time ensuring that all relevant risks are managed. This would be the *lex specialis* principle in indent 1 in the list above in section 4.9.2 (Background), which would cause the MDR / IVDR to be the only regulation to apply for design, safety and performance requirements of medical devices. The MDR / IVDR GSPRs are flexible enough to accommodate all known safety and performance requirements and the MDR should, as most specific legislation applicable for medical devices and based on its public health goals have precedence as *lex specialis*. Where the MDR / IVDR GSPRs are lacking or address certain specific risks they can easily be amended by means of an implementing act.¹⁰¹ Where standardization is lacking for a specific GSPR this can be provided by means of Common Specifications.¹⁰²

Where the opinion in indent 1 in the list above is not feasible from a policy perspective indent 2 is a reasonable alternative and a proven solution for managing overlap in the MDR / IVDR.

The MDR and IVDR should be amended to limit national ‘solutions’ by Member States during roll-out of legislation and the Commission should actively engage with Member States when they introduce such new measures, even if these are intended to be temporary. Where MDR and IVDR roll-out requires Commission resources (such as Eudamed) these project should be appropriately resourced and managed to account for their strategic importance.

5 Reform of certification cycle

5.1 Reform of (re-)certification process of MDR and IVDR devices

5.1.1 Issue

The CE certificates issued by notified bodies for devices are currently limited in duration to five years, which necessitates re-assessment for a renewed certificate every five years. When a notified body – as happens more and more – is unable to finish recertification before expiry of the certificate the manufacturer is forced to cease placing devices on the market until the notified body has completed the certification procedure.

¹⁰¹ Article 5 (6) MDR / IVDR provides a legal basis for this

¹⁰² Article 9 MDR / IVDR

Under the IVDR an enormous amount of devices has been made subject to notified body certification compared to the IVDD, creating instant critical congestion in the conformity assessment system.

5.1.2 Background

An MDR or IVDR device certificate has a maximum duration of five years, after which the conformity assessment must be repeated for certification extension.¹⁰³ However, this five years duration is justified nowhere in the MDR or IVDR, nor was it subject of discussion when the MDR and IVDR were adopted.¹⁰⁴

During the current five years duration the certificate is subject to annual surveillance audits, possible unannounced audits and the manufacturer has to periodically provide PSURs to the notified body.¹⁰⁵ In addition, a significant and substantial change to the product must be specifically indicated, checked and approved in a separate procedure. The QMS must ensure that the clinical / performance evaluation remains aligned with the state of art over time.¹⁰⁶ Based on article 61 (12) and 83 MDR and articles 56 (2) 78 IVDR the technical documentation and underlying clinical / performance evaluation must be continuously updated with data sourced from a large number of relevant sources to ensure that the device is continuously compared to the state of the art in clinical practice and competitor devices. All these processes provide for input about whether the device remains state of art over time as is required under Annex I, 1 MDR and IVDR (a positive risk/benefit balance must remain positive over time). As a result, a periodic re-assessment and re-issuing of the certificate duplicates notified body activities, because it requires among other things¹⁰⁷:

- Re-assessment of all changes to the originally approved device, including changes not notified (in other words: changes that have already been evaluated when reported by the manufacturer are evaluated again, and changes that did not need to be evaluated before implementation are evaluated nonetheless); and

¹⁰³ Article 56 (2) MDR / 51 (2) IVDR

¹⁰⁴ The duration is not discussed as an option anywhere in the Impact Assessment (SWD(2012) 274 final)

¹⁰⁵ Article 86 MDR and 81 IVDR; in addition manufacturers of class I devices / class A and B IVD devices must prepare (but not submit) post-market surveillance reports that are kept available to the competent authorities pursuant to article 85 MDR / 80 IVDR

¹⁰⁶ Annex IX, 2.1 last indent and Annex XIV (1) (a) 6th indent MDR / Annex XIII (1.1) 10th indent IVDR

¹⁰⁷ Annex VII, 4.11 MDR and IVDR

- Assessment of experience from PMS, PMCF/PMPF and risk management (in other words, re-assessment of information already provided to the notified body in PSURs¹⁰⁸)

There is no requirement for medicines to have the marketing authorisation re-issued periodically. Once issued the validity of the marketing authorisation is indefinite, provided that the marketing authorisation holder applies the agreed pharmacovigilance plan and variations are notified and assessed by the authorities. There is no periodic duplication of assessment of pharmacovigilance data or variations in an overall marketing authorisation re-assessment.

Also, medical devices market approvals in other markets like the US do not need to be periodically re-issued based on a review of the device against the then current state of the art as is required for EU CE certificates for devices.

For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD: 736%.¹⁰⁹ This policy decision has not been motivated by safety or performance issues with IVDs under the IVDR and does not serve a purpose of increasing patient safety or test performance. As a result, the conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment¹¹⁰ but for which notified body capacity under the IVDR is scarce and of which the added value of notified body conformity assessment is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased performance or safety of tests. The Impact Assessment for the IVDR stated that adoption of the GHTF classification structure for IVDs would necessarily mean conformity assessment for class B devices by a notified body.¹¹¹ This does however not follow as a necessary option from GHTF recommendations for IVD conformity assessment, as these also allow for competent authority ex-post supervision on this point as an alternative to notified body assessment.¹¹² Accordingly, this has been an EU policy choice, which may be revisited. There is all the more reason to revisit this

¹⁰⁸ See article 86 MDR / 81 IVDR

¹⁰⁹ MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies, 8 September 2021, p. 2 (<https://www.medtecheurope.org/wp-content/uploads/2021/09/medtech-europe-survey-report-analysing-the-availability-of-in-vitro-diagnostic-medical-devices-ivds-in-may-2022-when-the-new-eu-ivd-regulation-applies-8-september-2021.pdf>)

¹¹⁰ Class B IVDs were estimated to comprise about 50% of the IVDs on the European market at the time of the Impact Assessment for the IVDR in 2012, see Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 16

¹¹¹ Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 15-16

¹¹² GHTF/SG1/N046:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices, p.

choice and calibrate its consequences, because the expected benefits of the implementation of the GHTF risk classes have not led to the benefits justifying this policy choice that were expected in the Impact Assessment. The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on “enhanced robustness of the classification system, as well as international harmonisation”.¹¹³ So far the advantages that underly this policy choice have not materialized and BVMed and VDGH do not expect them to materialise without recalibration of the IVDR’s certification process.

5.1.3 Solutions for discussion and opportunities

Extension of standard certificate duration or automatic renewal

Since there is no objective justification for a five-year certification duration in the case of devices and the MDR and IVDR have significantly increased PMS (including PMCF-PMPF activities) to ensure continued compliance of the device throughout its life cycle, certificates should have unlimited duration (subject to PMS and PMCF/PMPF) or at least substantially extended and duplication of activities in re-assessment should be avoided.

A certificate, once granted, should be subject to the many PMS controls under the MDR and IVDR only and should not be subject to periodic renewal. Where a device performs as intended and the manufacturer demonstrates this on a continuous basis with PMS and PMCF/PMPF data, there is no reason to periodically revisit the certification decision and the certificate can continue to be valid subject to appropriate surveillance by the notified body.

Continued certificate validity should rather be risk and data based, based on PMS and PMCF/PMPF performance by the manufacturer as monitored by the notified body. If the manufacturer’s PMS and PMCF/PMPF real-world data show that the device performs as intended after CE marking and to the state of art as is required under MDR or IVDR PMS and PMCF/PMPF requirements, there is no objective reason to repeat the certification and the notified body can earmark a certificate as in good standing without need to be re-issued. Manufacturers and notified should be granted access to secondary data available for example in national registries clinical performance databases kept by health institutions for reimbursement purposes and other relevant sources of data to better meet Article 83 (3) MDR / 78 (3) IVDR PMS objectives, such as contributing to the PMS of other devices, trend detection and reporting and identification of options to improve aspects of the device. Access to a broader scope of real-world quality data that is already available would benefit all

¹¹³ Impact Assessment SWD(2012) 273 final, PART III - Annex 2, p. 22

parties with an interest in PMS for devices: the patient, the authorities and the manufacturers. This is discussed in detail below in section 5.2 (PMS).

Non-duplicative certificate renewal

In cases where an extended (e.g. 10-year) certificate duration would be opted for, the re-assessment for extension should not duplicate activities and should be risk based and leverage existing evidence to the maximum extent as is also foreseen for MDR and IVDR conformity assessment applications in MDCG 2022-14. In the cases where the device has continuously performed to the state of art for the device as this evolved over time it should not be needed for the CE certificate to be reissued based on conformity assessment against the then current state of art. Rather, the large amount of PMS and PMCF/PMPF information that manufacturers have to collect and share with a notified body should be used as a basis to determine if there is reason to believe that the device is not state of art anymore or has started to pose a threat to health and safety over time.¹¹⁴

Repeating of the conformity assessment for certificate renewal should become a 'for-cause' process where conformity of the state of art is not supported sufficiently. Causes that would warrant recertification could be open non-conformities or pending vigilance reports, basically causes that would warrant scope reduction or suspension of the certificate.

No expiry of certificates during recertification process

There are known cases where the notified body moved audit dates repeatedly as a result of its own internal planning and then forced the manufacturer to purchase an expedited review because there was not sufficient time left to complete recertification before expiry of the certificate. This left the manufacturer with only that option to avoid not being able to place devices on the market for an unknown period of time. To avoid scenarios like this the MDR and IVDR should be amended with a rule that a certificate for which a notified body has started the recertification process cannot expire until the recertification procedure is finished. The notified body can then be audited on its ability to recertify before expiry of the certificate, but this should not be made the manufacturer's problem, as this causes damage to the manufacturer and undermines trust in the system.

Variation process for M&A

Re-issuing of the certificate is currently needed in case of mergers and acquisitions (M&A) activity that involve a change of the identity legal manufacturer (such as

¹¹⁴ By analogy to the condition in article 120 (3c) MDR for continued validity of extended legacy device certificates under the MDR.

typically in an asset purchase), which leads to unnecessary formalities as these changes are currently seen as a significant change under the MDCG 2020-3 Rev 1 (MDR) and MDCG 2022-6 (IVDR). There should be a simplified process for transfer of certificates within a single quality system or for transfer of the certificate as part of an asset transaction as to support corporate housekeeping and M&A by means of asset transactions, analogous to the variation process for medicines. Alternatively it should be possible for the acquiring manufacturer to submit an application for a substitute device by analogy to article 120 (3) MDR as amended, both under the MDR and IVDR.

Summary of Safety and Performance

Article 29 IVDR requires preparation and publication of a Summary of Safety and Performance for all class C and D IVDs with the goal of informing the user and patient. This presents an enormous administrative burden for manufacturers and notified bodies, who need to prepare, compose, evaluate and validate these reports. In practice only lay user tests (self-tests) would have a need for lay user presentation of information about safety and performance. Patients are not concerned with the performance of tests ordered for their samples by healthcare professionals for which the patient receives quantitative or qualitative results. These tests are interchangeable to the professional user and therefore not subject to a discussion with the patient. Any information on the test results, without healthcare professional interpretation, raises additional risk of misinterpretation. In that sense there is a marked difference between an IVD with which a patient sample is tested and a permanent implant of a patient to restore mobility. In the latter case the patient has a much more direct interest in a lay version of the Summary of Safety and Clinical Performance to know what to expect from the device's performance. Furthermore, professional IVD users rely on the information in the IFU for the test, which is subject to Post-Market Surveillance and must be adapted if there are any changes to safety or performance relevant for the user of the test. Following this rationale an SSP it is very unlikely to be used by a patient and user. The administrative burden can be significantly reduced by not requiring such a document.

Self-assessment for class B devices

Removing class B devices from the requirement of notified body conformity assessment pursuant to article 48 (9) IVDR would create much needed relief of congestion in the conformity assessment process and unnecessary costly formalities for class B devices. This was also originally foreseen in the IVDR proposal in article 40 (4).¹¹⁵ The requirement of sampling of technical documentation in article 48 (9) IVDR

¹¹⁵ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0541:FIN:EN:PDF>; see also p. 6 of the Explanatory Memorandum in the proposal.

was added later. Removing the sampling requirement would free up the resources to allow both manufacturers and the few available notified bodies to concentrate on conformity assessment of more complex and/or higher risk devices for which where notified body conformity assessment has added value from a performance and safety perspective: the class C and D devices.

5.2 Post market surveillance

5.2.1 Issue

Manufacturers must collect vast amounts of PMS and PMCF/PMPF data under the MDR and IVDR, most of which pursuant to rigid one-size-fits all procedures applicable to a device regardless of its stage in the lifecycle, leading to high costs of compliance and production of data that is not leveraged optimally in practice. As was discussed above in section 5.1.3, an additional complication is that high-quality data that is collected and available in the healthcare system cannot be used as secondary data for PMS purposes.

5.2.2 Background

At the moment the MDR and IVDR impose a significant increase in requirements for PMS compared to the (AI)MDD and IVDD that requires a significant additional investment from the manufacturer in RA/QA capacity to complete all the additional tasks and reports required under the MDR and IVDR, such as SSCP/SSP, PSUR, PMCF/PMPF information collection and the long (not even closed) list of objectives of the PMS programme set out in article 83 (3) MDR / 78 (3) IVDR. While there is a degree of differentiation in requirements by risk class, the system is mostly a one-size fits one-way all information gathering exercise that is very labour intensive without a clearly thought-out strategy about the use of all data generated.

Yet, the main objectives of PMS under the MDR and IVDR remain for the manufacturer to actively gather PMS data to update the technical documentation and make vigilance notifications in case of serious incidents.¹¹⁶

5.2.3 Solutions for discussion and opportunities

The PMS process should be capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned. PMS and PMCF/PMPF should not be about producing data and putting this in reports but rather about detecting signals relevant to PMS and PMCF/PMPF. As discussed above in section 5.1.3 clinical performance

¹¹⁶ Recital (74) MDR / (75) IVDR

and real-world data that is already available from various sources in the market should be leveraged more effectively. For example, PMS processes under the MDR and IVDR could benefit greatly from manufacturer access to device performance data collected in European Health Data Space frameworks (such as PROMs, PREMs and RWD¹¹⁷) for secondary use for PMS and PMCF/PMPF purposes.

Manufacturer access to such data for these purposes would allow patient outcomes related to devices to be improved in accordance with the existing MedTech Europe position on the European Health Data Space.¹¹⁸ Confidentiality of data and secondary use of personal data can be managed for this purpose within the legal framework provided by articles 109 and 110 MDR / 102 and 103 IVDR, which require that parties keep personal data obtained for carrying out their tasks under the MDR and IVDR confidentially and process any personal data in accordance with GDPR¹¹⁹ requirements.

Key Risk Indicators (KRIs), baselines and stratification criteria¹²⁰ could be defined for groups of devices by the MDCG or by the notified bodies in cooperation with stakeholders. KRIs could also be defined for types of input, such as patient and user reports, which would allow better trending of potential misuse.

The MDCG could further refine its PSUR related grouping guidance in MDCG 2022-21 and provide additional guidance on the definition of ‘significant increase’ in article 88 (1) MDR / 83 (1) IVDR. This would allow for better calibration of methods required under Part B, point 6.1 of Annex XIV MDR / Part B, point 5.2 of Annex XIII IVDR.

This would not only lead to a vast increase of comparability of data between manufacturers within a specific device group but it would also ensure that only relevant data is captured and analysed. PSURs could have a standard XML format that can be populated as to provide input for a periodic rolling dashboard of information. The XML format will allow comparison of devices and overall trending in Eudamed, once the vigilance and PMS module is active.

¹¹⁷ Patient-reported outcomes measures (PROMs), patient-reported experience measures (PREMs), surgical audios/videos, and real-world data (RWD), which all comprise data that manufacturers are instructed to collect under the MDR for PMS and PMCF / PMPF purposes.

¹¹⁸ <https://www.medtecheurope.org/wp-content/uploads/2023/02/230222-ehds-position-paper-final.pdf>

¹¹⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L119/1

¹²⁰ Stratification is a data collection and analysis technique that separates the data so that patterns can be seen and the root cause of the excursion of the trended metric can be discovered because the different strata of data are analysed separately. Stratification helps in resolving the signal into its source components so the manufacturer can check the sources in terms of their contribution to the signal.

The PMS plan could then focus on justification of the methodology, KRIs and baseline for the device concerned, leading to more relevant and comparable PMS and PMCF/PMPF results. This improved PMS plan could be the basis for supporting continued validity or for automatic certificate renewal as discussed above in section 5.1.3.

6 International cooperation and reliance

6.1 EU participation in the MDSAP

6.1.1 Issue

The EU does not recognize MDSAP reports, as a result of which a full QMS audit under MDR and IVDR standards always remains necessary even if a manufacturer has been audited under the MSDAP program (although MDSAP reports can be taken into account only to an extent and not for initial MDR / IVDR or unannounced audits¹²¹), leading to duplication of auditing and reporting efforts and associated costs.

6.1.2 Background

MDSAP allows for a single audit of a medical device manufacturer's QMS, which satisfies the requirements of the participating regulatory jurisdictions. At the moment several large jurisdictions are MDSAP members and recognize MDSAP reports (US, Australia, Canada, Brazil and Japan), but not the EU. Conversely, a QMS audit report under the MDR or IVDR is not recognized in MDSAP jurisdictions. While the EU states in the MDR and IVDR that it wants to promote international convergence of medical devices regulations, including conformity assessment procedures¹²², the EU is not a member of MDSAP. Several Union notified bodies are already recognized Auditing Organizations (AO) to audit under MDSAP requirements. So far the EU has been observer in the MDSAP (pilot) because of concerns it would be difficult to obtain agreement among all Member States. It is uncertain if and when the EU will join MDSAP.

MDCG 2020-14 provides guidance to notified bodies with guidance on how to take MDSAP reports into account for MDR and IVDR QMS reviews. Since notified bodies designated under the MDR or IVDR fulfil both the AO as the Regulating Authority (RA) role, the roles performed by notified bodies and MDSAP AOs differ. The use of MDSAP audit reports within the EU legislative framework is possible only where the

¹²¹ MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR), p. 3 and 4

¹²² Recital (5) MDR / IVDR

MDSAP audit covers similar or equivalent MDR or IVDR requirements. At the moment the audit model used for MDSAP does not incorporate all requirements from the MDR and IVDR.

Notified bodies must work on their normal surveillance audit cycle but may take MDSAP report results into consideration after which they can make an assessment of the gap with MDR or IVDR requirements not or partially covered in the MDSAP report.

6.1.3 Solutions for discussion and opportunities

The MDCG seems to make an artificial distinction between the nature of notified bodies and AOs under the MDSAP. Not only is it theoretically possible to combine a QMS certificate of one notified body with a conformity assessment of another notified body under the MDR or IVDR, notified bodies also typically issue a separate QMS system and product conformity certificate under the MDR or IVDR.

The intention behind the MDSAP model is to allow an AO to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.¹²³ While some of the MDSAP members accept MDSAP audit as fully meeting the regulatory requirements, others accept MDSAP reports as meeting part of the regulatory requirements. Given the rationale in MDCG 2020-14 that notified bodies can already take MDSAP reports into account (but just not rely on them as such) and the fact that some notified bodies are AOs for MDSAP purposes as well, there is no objective reason why the EU could not close the gap to accept MDSAP reports as a standard element of QMS requirements. Rather than leaving definition of a gap between the MDSAP report and an MDR or IVDR QMS audit to each notified body the EU could define standard gap between MDSAP audit scope and full QMS audit scope under the MDR and IVDR. This would allow the EU to become a full participant in MDSAP as well as to participate more fully in the IMDRF MDSAP activities that are aimed to arrive at a single IMDRF audit program as promoting global convergence of medical devices regulations through the IMDRF is a specific EU goal under the MDR and IVDR.¹²⁴ It would allow the EU to export MDR and IVDR QMS audits under the MDSAP program, making the MDR and IVDR more relevant internationally.

¹²³ <https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap>

¹²⁴ Recital (5) MDR / IVDR

6.2 International reliance

6.2.1 Issue

While medical devices are generally of the exact same design everywhere in the world, manufacturers must obtain separate market access approval in each jurisdiction under different local rules with different regulatory logic. This leads to an enormous administrative burden and delays in market access, depriving patients of medical technology that is available but cannot be provided because of formalities. As a result of increased formalities and bottlenecks within the implementation of the regulations the Union is at risk of losing its position as market of first launch for (innovative) medical devices and IVDs.

6.2.2 Background

The CE mark has been very successful as a regulatory export product and many countries have attached importance to the CE mark as a benchmark for local approval and registration purposes. The Union was also the jurisdiction of choice for the first launch of new medical technology because of the efficiency of the approval system and the high standards that underpinned the CE mark as a basis for third country approval. However, as a result of the issues with the MDR and IVDR transitional regime and scarcity of notified body capacity the CE mark is increasingly losing international importance and the Union market is losing its attractiveness as medical devices manufacturers that seek to obtain regulatory approval in Europe first are confronted with an inefficient, costly, unreliable and congested approval system. Approximately 50% of respondents to MedTech Europe's April 2022 survey are deprioritising the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices under the MDR.¹²⁵ Under the IVDR MedTech Europe's data shows a 28% drop in manufacturers who would prioritise the EU for first product launches.¹²⁶

In addition, countries currently recognising CE mark are more and more considering relying on and/or recognising approval from other jurisdictions, notably the US with FDA approval.¹²⁷

Since most devices are not designed and produced for the Union market alone there is a potential for enormous efficiencies if the EU and other jurisdictions with a mature regulatory system for devices such as the US increase reliance on each other's approval systems for medical devices. Mutual recognition of conformity assessment

¹²⁵ MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 14 July 2022, p. 3

¹²⁶ Transition to the IVD Regulation, MedTech Europe Survey Results for October 2022, February 2023, p. 3

¹²⁷ Notably Switzerland and Australia

could be an important reliance endpoint for enhancing market access between the EU and the US. More broadly the development of a Medical Device Single Review Program in the IMDRF would be an important driver for regulatory reliance in a global context.

Finally, there is development towards fragmentation in Europe with the UK and Switzerland having opted out of mutual recognition for devices, which makes Europe more and more fragmented as regards regulatory approval of devices with the UK working on its own UKCA mark based on the CE mark regulatory template and Switzerland unilaterally recognising the CE mark but taking steps towards FDA approval recognition.

6.2.3 Solutions for discussion and opportunities

BVMed and VDPH see many opportunities for the EU to further recognition- and reliance practices internationally and to promote international convergence of regulation both under existing structures and under new structures.

In dealings with other jurisdictions with a mature regulatory system for devices, the EU should facilitate the use of reliance and recognition mechanisms, as appropriate. Recognition according to the World Health Organization is the acceptance of the regulatory decision of another regulator or trusted institution.¹²⁸ Reliance is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.¹²⁹

International reliance can be promoted by exchange of PMS reporting, vigilance and market surveillance information.

Solving the current issues with the MDR and IVDR system

For the CE mark to regain its international reputation that has served the Union so well in the past, the issues created by the MDR and IVDR that have eroded the strategy of 'Europe first' for new medical technology need to be remedied. BVMed and VDPH have made recommendations and have raised points for discussion in this paper that will make an important contribution to restoring the efficiency of the

¹²⁸ WHO Expert Committee on Specifications for Pharmaceutical Preparation, 55th report, 2021, page 243 (<https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations>)

¹²⁹ WHO Expert Committee on Specifications for Pharmaceutical Preparation, 55th report, 2021, page 243 (<https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations>)

approval system without compromising on patient safety and performance of devices.

Continuing work on regulatory convergence at IMDRF level and beyond

Secondly, although the IMDRF and other collaboration platforms on regulatory convergence do not have as their goal to arrive at a situation of mutual recognition between their members, international harmonisation within the could lead to convergence of regulation that may facilitate opportunities for reliance and/or recognition. The EU could play a more active role in the IMDRF and other fora by strengthening the international reputation of the CE mark as a regulatory benchmark.

Reviving the existing EU-US MRA

Thirdly, an opportunity for reliance between the EU and the US and improvement of efficiency of patient access to medical devices is the Mutual Recognition Agreement (MRA) that is in place between the EU and the US, which dates back to 1999, which includes medical devices in its scope and applies in parallel to existing regulatory approval processes.¹³⁰ Specifically, it provides a structure for the EU and the US to accept the results of quality system-related evaluations and inspections and premarket evaluations of the other Party with regard to medical devices as conducted by listed conformity assessment bodies (CABs) and to provide for other related cooperative activities.¹³¹ In this regard the MRA closes the gap identified as regards MDSAP scope in MDCG 2020-14 as this MRA concerns full scope regulatory approval recognition and not only acceptance of QMS audit result.

The MRA recognises that carrying out its goals will further public health protection, will be an important means of facilitating commerce in medical devices and will lead to reduced costs for regulators and manufacturers of both Parties¹³², which it today still as relevant as it was in 1999. The MRA specifies the conditions by which the EU and US will accept or recognise results of conformity assessment procedures, produced by the other's designated conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified for medical devices on a medical device sector-specific basis, and to provide for other related cooperative activities.¹³³ The EU-US MRA already has been fitted officially into their cooperation with regards to harmonisation activities in the IMDRF¹³⁴ and establishes

¹³⁰ Agreement on mutual recognition between the European Community and the United States of America, OJ 1999 L31/3

¹³¹ Article 1 MRA Sectoral Annex on Medical Devices

¹³² Preamble of the MRA Sectoral Annex on Medical Devices

¹³³ Article 2 MRA

¹³⁴ Article 18 MRA Sectoral Annex on Medical Devices

a bilateral regulatory cooperation mechanism.¹³⁵ While there has been no significant activity under this MRA for medical devices so far, there has been a lot of activity with in the field of the sectoral annex on electromagnetic compatibility (EMC). The EU could endeavour to restart the process of confidence building activities under the devices sectoral annex of the MRA, leading up to the MRA entering its operation period and providing for actual mutual recognition of approval between the EU and the US.

The Commission should actively pursue MRAs with UK and Switzerland

Fourthly, the Commission should actively seek to prevent regulatory fragmentation at the EU frontiers and seek to maintain the Union geographic scope in which the CE mark applies for medical devices. This would mean active efforts to conclude or reinstate mutual recognition and reliance with the UK and Switzerland insofar as politically feasible.

A legal basis for international convergence and reliance

When implemented responsibly, international convergence and reliance is an efficient strategy for utilizing resources among mature regulators, while building regulatory expertise and capacity, and elevating speedy access to safe and effective, quality-assured medical devices. In the long term, the EU legislation needs a sufficient legal basis for such practices that apply across the total product lifecycle.

International exchange of vigilance and market surveillance data

Finally, the EU-US MRA provides for a comprehensive mechanism for exchange of PMS and vigilance data as well as an alert system for public health threats¹³⁶, as well as a wider framework for the exchange of confidential information between market surveillance authorities. Article 102 MDR and 97 IVDR on (international) cooperation could be amended with a specific mandate for the Commission to pursue such networks with third countries and other relevant international cooperation by analogy to the active international cooperation mandate granted by the Commission under article 50 GDPR. By analogy to article 50 GDPR such active pursuit of international cooperation should include appropriate stakeholder involvement.

¹³⁵ Article 19 MRA Sectoral Annex on Medical Devices

¹³⁶ Articles 3 sub 3 and 20 Sectoral Annex on Medical Devices: “Post-market vigilance reports will be exchanged with regard to all products regulated under both US and EC law as medical devices.” and “An alert system will be set up during the transition period and maintained thereafter by which the Parties will notify each other when there is an immediate danger to public health.”

7 Centralisation of responsibility

7.1 Structuring of certification procedures and self-certification

7.1.1 Issue

As a result of inefficiencies in the functioning of the current regulated market-based market access mechanism relying on decentralised notified bodies that are notified and supervised by single member states patients are deprived of medical technology that can improve their outcomes and manufacturers are deprived of predictable conformity assessment options. The joint assessment process under article 39 MDR and article 35 IVDR has failed and continues to fail to deliver the intended outcome of harmonisation.

7.1.2 Background

The option of centralisation of market access decisions was explicitly one of the policy options when the MDR and IVDR were conceived: “A central marketing authorisation (at EU level) would require building a new EU public body with a sufficiently skilled staff to assess devices, similar to the US FDA. It would have significant impact on the EU budget, on manufacturers in terms of costs and administrative burden and on innovation in terms of time to market.”¹³⁷

There was a modest support for this policy option at the time from mainly the public sector and healthcare insurance funds, but especially industry stakeholders were opposed to that option.¹³⁸ Also, the Commission was not convinced that a central agency would have prevented the PIP scandal.¹³⁹ Therefore the Commission concluded at the time that “such a radical shift in the regulatory system would be inappropriate.”¹⁴⁰

BVMed and VDPH believe that given the MDR’s and IVDR’s performance so far, there is reason to revisit the philosophy of decentralisation under the "New Approach" as this approach has not turned out optimal under the MDR and IVDR.¹⁴¹ The same is true for the assumption at the time that a pre-market authorization procedure by regulatory authorities with longer deadlines and higher fees (EMA was given as an

¹³⁷ Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7

¹³⁸ Impact Assessment, Part I (SWD(2012) 274 final), p. 28; see also Impact Assessment, Part IV (SWD(2012) 274 final), p. 3: “The rejection of a larger role for EMEA by the vast majority of respondents was mainly based on the fear that the involvement of EMEA would represent a move towards the adoption of a pharmaceuticals-like regulation for medical devices. Such an approach could lead to undue delays and higher costs for placing new devices on the market which, according to the majority of contributions, would have an adverse effect on SMEs, which make up around 80% of the sector.:

¹³⁹ Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7

¹⁴⁰ Impact Assessment, Executive Summary (SWD(2012) 274 final), p. 7

¹⁴¹ Impact Assessment, Part IV (SWD(2012) 274 final), p. 5

example) would not increase public health, but would be detrimental to the competitiveness and innovativeness of the industry, and thus ultimately be against patients' interests.¹⁴² Also this assumption has not been proven necessarily true for the MDR and IVDR. Rather, the system would benefit from centralisation of responsibility and policy in a central European governance structure.

The regulated market-based system of outsourcing market approval decisions to notified bodies has allowed the Member States' competent authorities to limit themselves to a role of (post) market surveillance that requires relatively little resources from them (compared to for example medicinal products authorisation surveillance). This has led to historic under-resourcing of medical devices competent authorities by Member States and of the medical devices policy function at the European Commission, creating a situation in which the existing medical devices structures are not adequately resourced for the work that society expects of them. This has become painfully clear with the amount of work required for implementation and administration of the MDR and IVDR where the system clearly has underdelivered. Currently the system does not produce the desired outcome for any of the stakeholders involved: not for patients, not for Member States, not for competent authorities, not for the Commission, not for notified bodies, not for industry and importantly not for the patients. The system does not meet its public health and internal market goals anymore and the structure set up under the MDR and IVDR has proven unable to remedy this so far as a result of its decentralised nature. For example, even welcome and widely agreed policy initiatives like set out in the MDCG 2022-14 position paper take far too long to first mature and then to be implemented and executed.

The (re-)designation process for notified bodies under the MDR and IVDR has performed absolutely below standards. A large part of the problem is the slow process relying on a combination of the JAT and the notifying Member State, which is very inefficient, time consuming and does not concentrate the relevant experience.¹⁴³ Notified bodies have had to embark on a massive recruitment exercise

¹⁴² Impact Assessment, Part IV (SWD(2012) 274 final), p. 5

¹⁴³ See Commission Information note for EPSCO meeting, 8 March 2023, 6484/23, p. 4: "The Commission is offering its assistance to national designating authorities to gain efficiency in the process. The Commission has also offered additional supports to national designating authorities and applicant conformity assessment bodies in relation to the corrective and preventive action phase of the joint assessment procedure (the most lengthy phase of the process). At the same time, the Commission notes that for 6 applications, designating authorities have not yet submitted their preliminary assessment reports, which are needed to launch the joint assessment phase. The Commission therefore calls upon all designating authorities to submit outstanding preliminary assessment reports without undue delay. According to the relevant MDCG best practice guide, the estimated time to complete such a preliminary assessment is three months but current waiting times for submission vary from a few weeks to 18 months, in some cases up to 24 months. The Commission also commits to shorten its reaction time wherever possible."

to increase FTEs for processing all conformity assessment applications for devices that were already approved under the Directives¹⁴⁴, massively adding to their costs of operations and, consequently, fees for manufacturers. Also, although there may be a small degree of harmonisation brought about by the process as currently set up, in practice more harmonisation can be achieved by concentrating expertise and experience in one place at a central accountable managing structure.

Attributing a central accountable managing structure with competence to take market access decisions for medical devices has the problem that the accountable managing structure will likely not have the capacity and technical competence to deal with assessment activities for all devices in scope of the MDR and IVDR in all risk classes or for all types of procedures. As a result it would not be possible to make the accountable managing structure responsible for all possible categories of devices and the notified bodies would need to continue to play the important role that they currently play with respect to conformity assessment of devices. This allows the system to be able to deal with the larger volume of devices that pose no particular problems because the technology is well-understood and there is sufficient clinical evidence.

7.1.3 Solution

Establishing a central accountable managing structure for medical devices would have important advantages over the current system. It would lead to a scenario where good administration is applied to decisions concerning certificate grant and certification status, just like with medicinal products and as is actually required under the EU Charter of Human Rights and the European Convention on Human Rights (ECHR). An accountable managing structure would have a transparent and fair single rate structure that can compensate for SMEs or special devices such as niche or orphan devices like the EMA fee structure. A single fair and transparent rate structure combined with predictable deadlines for procedures subject to principles of good administration would serve public interest better for the devices in scope of the accountable managing structure.

BVMed and VDPH do not have a preference as to the organisation of the accountable managing structure. If this is to be set up as a singular entity BVMed and VDPH believe that it should be set up as a standalone EU agency (and not as a branch of the EMA) for oversight of the Union medical devices policy and approval of certain devices based on the EU template for a 'decentralised agency'.¹⁴⁵ Although the EMA currently

¹⁴⁴ See Team NB survey 2022, slide 27 (<https://www.team-nb.org/wp-content/uploads/members/M2023/Survey-2022-20230411.pdf>)

¹⁴⁵ https://european-union.europa.eu/system/files/2022-06/joint_statement_on_decentralised_agencies_en.pdf

has limited involvement in the application of parts of the MDR and IVDR and administrates certain processes, the EMA is and remains a medicines agency. The medical devices policy elements already administrated by EMA should be transferred to the accountable managing structure.

The same structure could be used as is currently used for EMA medicines marketing authorisation procedure: the EMA issues an advice and the European Commission takes the formal decision, allowing for appeal to the General Court.

Because the accountable managing structure will not have the capacity to deal with market access for all risk classes and types of devices it would be opportune to restrict the competence of the accountable managing structure for certification to certain specific minority of devices and/or specific roles in the approval process. The remainder would be subject to certification decisions by notified bodies. There was support for such a blended model in 2012 when the MDR and IVDR were conceived.¹⁴⁶

The accountable managing structure could for example provide certification decisions for devices currently in scope of the clinical evaluation consultation procedure under article 54 MDR and the scrutiny procedure under article 50 IVDR.

The accountable managing structure would have a framework for engagement with patients and consumers that can be modelled on the EMA patient engagement framework to ensure that the patient voice is included in the different regulatory activities of a device's lifecycle. This will improve the quality of and trust in the regulatory decisions and in new devices placed onto the EU market.¹⁴⁷ In addition, the accountable managing structure would need to allow for engagement with other stakeholders, notably manufacturers and notified bodies.

The accountable managing structure, as discussed in this White Paper, can consolidate responsibility for a number of indispensable roles and responsibilities for the functioning of the Union medical devices regulatory system, such as:

- an SME office by analogy to the EMA SME office;
- monitoring notified body fees and providing harmonisation of fees structures for notified bodies;
- an administrative appeal instance for appeal against notified body decisions regarding (non)grant, suspension, restriction of revocation of CE certificates;

¹⁴⁶ Impact Assessment, Part IV (SWD(2012) 274 final), p. 9-10

¹⁴⁷ https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-patients-consumers-their-organisations_en.pdf

- taking over tasks from the MDCG and the Commission such as guidance development, harmonisation of notified body auditing, notified body oversight, integration of processes and development of EUDAMED; and
- overseeing designation, quality control and renewal of designation of notified bodies as well as coordination and harmonisation of notified body policy, consolidating responsibility for this process and notified body policy harmonisation in a single place. This would relieve pressure of under-resourced processes of the JAT, which have consistently posed a major, if not the biggest, bottleneck in the notified body designation process under the MDR and IVDR.

Another policy option in the Impact Assessment was the “Systematic ex ante control of conformity assessment reports for specific device types” (policy option 1F).¹⁴⁸ This option would oblige Notified Bodies to systematically submit their preliminary conformity assessment reports for certain devices or technologies to an expert panel (e.g. under supervision of the accountable managing structure) for scrutiny before a certificate could be issued.

On the basis of a number of criteria, the Commission could specify in a delegated or implementing act which device types would be submitted to a systematic prior scrutiny. The criteria to define those device types could be the following:

- new technology, i.e. a breakthrough technology which may have a significant clinical impact;
- "high risk" due to components or source material (e.g. tissues) or due to the impact in case of failure;
- increased rate of incidents;
- existence of significant discrepancies in the conformity assessment carried out by different Notified Bodies;
- existence of public health concerns regarding a specific device type or technology.

Within a predefined standstill period (e.g. three months), the accountable managing structure could raise concerns which would have to be taken into account by the Notified Bodies. This policy option would lead to harmonization of various aspects related to the underlying clinical data for the devices in scope, such as the level of clinical data required.

BVMed and VDPH believe that concentrating expertise at the accountable managing structure would be a preferable option because of the limited resources and FTEs

¹⁴⁸ Impact Assessment, Part I (SWD(2012) 274 final), section 4.4.3.2

available to DG SANTE and to Member State authorities for devices policy. The accountable managing structure could and should be adequately resourced from the start to be able to play a central role in the much needed procedural harmonisation of EU medical devices policy and conformity assessment and, to that end, consolidate the responsibilities necessary for this to succeed in one place.

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