Joint implementation and preparedness plan for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

This Joint Implementation Plan is the result of review by the MDCG including the relevant sub-groups, with input from stakeholders. It has been endorsed in principle in the MDCG meeting of 28 May 2021. In addition to setting the priorities, the Plan will serve as a living document to monitor their implementation. The status and timelines of the items will be updated to reflect the progress of the work.

March 2022

I. Introduction

A **new legislative framework** on medical devices, comprising Regulation (EU) 2017/745 on medical devices (MDR)[1] and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)[2] was adopted by the Council and the European Parliament in April 2017. This new framework sets high standards of quality and safety for medical devices and aims at ensuring the smooth functioning of the internal market. The MDR was envisaged to apply from 26 May 2020[3]. In contrast, the IVDR has a date of application of 26 May 2022. In March 2020, the Medical Device Coordination Group (MDCG), composed of experts appointed by Member States, endorsed a joint implementation plan on the implementation of the MDR. The plan listed priority actions for the Member States and Commission services, to be monitored at the level of the MDCG. The MDR joint implementation plan recognised the need to carry out a similar exercise for the IVDR. The present document therefore proposes a draft joint implementation plan for the IVDR.

The short transitional period originally envisaged for the application of the MDR (3 years) is in the interest of patient safety and in response to scandals with defective medical devices in the past. It aims to ensure that the strengthened requirements of the new framework apply as soon as possible. The IVDR pursues the same objectives but has a longer transitional period of 5 years. This is to allow more time to introduce many fundamental changes in the way the sector operates: among others, a new device classification system, much greater involvement of notified

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176–332.

[3] The application date was postponed to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, OJ L 130, 24.4.2020, p. 18–22.

bodies in conformity assessment of devices, new regulatory structures such as the EU reference laboratories and expert panels. The European Parliament and the Council of the EU as co-legislators chose the length of the transitional period to make sure that the EU IVD conformity assessment system is reinforced as early as possible. The COVID-19 pandemic has further illustrated the need for a robust framework that ensures high standards of quality on the EU diagnostics market.

The **implementation of the IVDR has proven to be a very challenging task** for the whole sector and all concerned: stakeholders, the European Commission and Member States.

The IVDR assigns many implementation tasks to the Commission. Other tasks are to be done by Member States to ensure that provisions are effectively applied and enforced at national level. The MDCG was established to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of the MDR and the IVDR. Relevant stakeholders have observer status at the MDCG. Together with its sub-groups, the MDCG serves as a platform to facilitate cooperation between Member States and the Commission, to ensure a coordinated approach among the Member States and to collect input from relevant stakeholders. The IVD sub-group in particular has the mandate to provide assistance to the MDCG on all IVD specific issues, in collaboration with other relevant sub-groups, notably the Notified Bodies Oversight sub-group.

Member States and the Commission have, together with relevant stakeholders, been working very hard to ensure effective implementation of the new rules. **Significant progress** has been achieved. For example, the necessary implementing acts and administrative arrangements enabling the designation of notified bodies have been put in place. Six notified bodies have been designated as of January 2022 and further applications are being processed. The Unique Device Identifier system has been set up. The Eudamed database is under development. The IVD expert panel has been designated and experts appointed. A number of new common specifications are in development. Many guidance documents either have been published or are in a mature preparation stage.

The transition represents a significant challenge also for **stakeholders** such as manufacturers, notified bodies, authorised representatives and laboratories. Many are very advanced in their preparation for compliance with the IVDR, engaging in tasks such as revising documentation in line with the new requirements, recruiting new staff and updating their procedures.

Despite the efforts undertaken by all, the implementation of the IVDR remains a serious challenge. It was compounded in 2020 by the additional efforts undertaken by all actors to respond to the COVID-19 pandemic. EU stakeholder organisations have reported that significant uncertainty hampers planning and preparation of their members for compliance with the IVDR.

Following the Commission proposal of October 2021[4], Regulation (EU) 2022/112 of the European Parliament and the Council of 25 January 2022[5] extended the

[4] COM(2021) 627 final

[5] 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 L 19, 28.1.2022, p. 3–6.

transitional provisions of the IVDR to smooth the transition from Directive 98/79/EC to the IVDR and to prevent disruption in the supply of essential in vitro diagnostic medical devices. The overall date of application of the IVDR remains the same, but the Regulation foresees staggered transition periods for devices placed on the market under Directive 98/79/EC by class (26 May 2025 for devices that fall in class D under the IVDR, 2026 for class C, 2027 for class B and A sterile). It also defers certain provisions for in-house devices (those manufactured and used in the same health institution, see Article 5(5) of the IVDR).

Ensuring patient access to safe and effective IVDs must be the focus of the implementation efforts. Member States and the Commission, together with concerned stakeholders, have **a joint responsibility** to ensure that the new legislation is operational from 26 May 2022.

To meet the challenges related to implementation of the IVDR, it is essential that **all actors** involved further step up their efforts and work closely together. This paper re-assesses the implementation priorities and sets out a **joint plan of the** Member States and the **Commission services, including concrete priority actions** in order to have an operational system in place before the date of application and provide key supporting elements as soon as possible.

The actions mentioned in this paper have already been identified as priorities and work on them is ongoing. The main aim of this paper, however, is to agree on where to focus **limited resources in the shorter term to ensure delivery as soon as possible and by the date of application**. The priorities set out in this document have been identified based on the **objectives of public health, patient safety and transparency**, which are key to the new legislation, as well as the most urgent needs of the stakeholders. The choice of priorities is further constrained by the fact that work to combat the COVID-19 pandemic must continue in parallel and therefore a resource balance must be found.

The priorities are split into **two sets**. Set A includes actions that are vital for devices to have access to the market (those related to a framework for contingency planning and availability of notified bodies). Set B includes legislation and guidance documents that, while not obligatory, would greatly facilitate the work of the actors as well as designation of EU reference laboratories for high-risk IVDs.

It should be recognised that focusing on a specific set of jointly agreed priorities could temporarily result in less resources being invested into other areas. While these short-term priorities are necessary now, they must be seen in the wider context of medium and longer-term actions for effective implementation and operation of the IVDR.

This Joint Implementation Plan is the result of review by the MDCG including the relevant sub-groups, with input from stakeholders. It has been endorsed in principle in the MDCG meeting of 28 May 2021. In addition to setting the priorities, the Plan will serve as a living document to monitor their implementation. The status and timelines of the items will be updated to reflect the progress of the work.

II. Priority areas and actions

Set A – essential actions

This section describes actions that enable contingency planning as well as those on vital infrastructure of the IVD sector, without which devices may not be placed in the market, notably the notified bodies.

1. Contingency planning and monitoring

As the date of application of the IVDR is approaching, the Member States and the Commission services are intensifying their work in coordinating activities, anticipating possible risks to device availability and taking appropriate measures. This work is already taking place at the level of the relevant MDCG sub-groups. Given the cross-cutting and critical nature of IVDR readiness, **a special focus** should be made for these discussions also **at the level of the MDCG**. The MDCG should discuss overall progress of the transition from the current Directive to the IVDR, analyse systemic risks to device availability and **identify solutions** to mitigate the risks, such as reprioritisation of work items, allocation of resources, emergency guidance or other measures. The MDCG may also engage in targeted monitoring as regards the availability of particular IVDs on the market and, in exceptional circumstances and in the interest of public health or patient safety or health, in communication regarding derogations from conformity assessment according to Article 54 of the IVDR[6]. To tackle these issues, the MDCG must engage in discussion more frequently than it has done so far.

It is essential that the stakeholders provide as much information as possible to enable the Commission and Member States to take action. In this respect, the Member States and the Commission services intend to continuously request **regular updates** from industry and notified bodies and to cooperate closely with Member States and stakeholders to identify potential problems early and find adequate solutions. In addition to quantitative information on stakeholder readiness, barriers to notified body designation and to the certification of devices by notified bodies should be identified. This information will feed into the discussions of the MDCG described above.

It goes without saying that full commitment is expected from all actors involved in the IVDR in ensuring their readiness for the application of the IVDR. In particular, as non-mandatory actions must be tackled in order of priority by the MDCG and Commission services, actors involved will need to manage some uncertainty in areas where guidance is not available and ensure that they develop sound justifications as to how they satisfy the requirements of the IVDR.

In practice, the application of the means to ensure availability of safe and critical devices to stay on the market need to be carefully considered with a view to ensuring

[6] Derogations referred to in Article 54 are possible from 26 May 2022, the date of application of the IVDR.

high protection of public health and patient safety through a sound application of the legal framework.

Lastly for this section, we may be faced with a deterioration of the COVID-19 crisis or with a new health crisis around May 2022, when the actors have relatively little experience with applying the new framework and not all guidance is fully developed. To ensure preparedness for such a scenario, an analysis of the IVDR should be carried out under a set of scenarios for a health crisis, notably a need for new devices of each of the four risk classes. Useful elements to reflect in this analysis would be the available emergency action tools, minimum timelines for conformity assessment of different kinds of devices, potential bottleneck steps related to the Regulation (e.g. function of notified bodies, supply of samples for EU reference materials, elaboration of new common specifications etc).

Priority actions:

1.1 Engage in an MDCG-level forum to communicate on critical issues related to IVDR implementation, on potential risks of shortages and measures taken to ensure availability of safe and critical IVDs. (Commission, MDCG)

1.2 Perform a market monitoring exercise to obtain as much data as possible on the preparedness of different stakeholders and aiming at detecting possible barriers that could lead to shortage of devices on the market (Commission, CAMD)

1.3 Analyse the IVDR in the context of hypothetical scenarios of an urgent response to a health crisis, scenarios to consider and methodology to be defined (Commission, MDCG IVD WG)

2. Availability of notified bodies

One concern related to the implementation of the IVDR is the **potential risk of shortages and disruption of supply of critical IVDs** due to the **lack of capacity for certification by notified bodies**. Their role is to assess the conformity of medium and high-risk devices against the IVDR requirements before they can be placed on the market. According to stakeholder estimations, under Directive 98/79/EC around 10% of all IVDs placed on the market need notified body involvement, whereas under the IVDR this will rise to 80-90%. Currently self-tests and devices listed in Annex II of Directive 98/79/EC must undergo certification by the notified bodies. The IVDR introduces a risk-based classification system with four device classes of increasing risk, A, B, C and D. Devices in classes B, C and D (as well as class A sterile devices) will require proportionate involvement of notified bodies. Devices listed in Annex II will become a subset of class D devices, those of highest risk.

19 notified bodies are currently designated under Directive 98/79/EC. Currently, **six notified bodies are designated under the IVDR**. Additional designations are in the

pipeline. It should be noted that the capacity of notified bodies may differ significantly among them, so the capacity should be taken into account when estimating the readiness of the sector. While it is clear that a greater capacity of notified bodies is needed under the IVDR compared to the IVDD, in the absence of information on the numbers of certifications needed, it is also not possible to predict what capacity of notified bodies will be sufficient to satisfy the demand.

Transitional provisions established in the IVDR, as amended by Regulation (EU) 2022/112, state that notified body certificates issued under the Directive 98/79/EC are valid, under certain conditions, until May 2025. In order to allow manufacturers to fully benefit from this transitional period, the 19 notified bodies designated under the current Directive have an important role in reviewing and renewing existing certificates, when necessary. Such renewals have to be finalised before 26 May 2022.

Regulation (EU) 2022/112 also introduced transitional provisions for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, and for which the conformity assessment procedure pursuant to the IVDR requires the involvement of a notified body. Under certain conditions, such devices falling in class D under the IVDR may be placed on the market or put into service until 26 May 2025, class C devices until 26 May 2026 and class B and class A sterile devices until 26 May 2027. To be placed on the market or put into service after those dates, they must have completed the conformity assessment by a notified body under the IVDR on time.

Any new devices that are not covered by a certificate or declaration of conformity under the IVDD, or devices referred to in the paragraph above that undergo a significant change in design or intended purpose must be CE-marked according to the IVDR to be placed on the market or put into service after 26 May 2022. They will need to undergo assessment by a notified body.

The monitoring exercise referred to in part 1 is key for keeping track of the proportion of manufacturers that have already submitted their applications to a notified body, and whether the capacity of notified bodies continues to represent a bottleneck for them.

Joint assessment of notified bodies is a key part of the designation process. As national experts are essential members of joint assessment teams alongside Commission staff, it is critical that Member States provide sufficient numbers of experts to take part in these assessments.

Notified body activity is affected by the COVID-19 restrictions, such as possible requirements to telework or restrictions on travel. This is particularly important for the IVD sector where a large number of first-time audits of manufacturers needs to be performed. Therefore this topic should be discussed on a continuous basis taking account of the evolving pandemic situation.

Results of recent industry and notified bodies surveys show a very significant gap between the work expected to be completed by notified bodies under the IVDR and

the total number of certificates issued[7]. The current situation requires further reflection to identify and concretely address root causes of lacking notified body capacity. The Member States and the Commission should assess the issue pragmatically, aiming at solutions that could help secure the needed availability of notified bodies, with a particular focus on avoiding delays in the designation process. This discussion should take place at the level of MDCG, involving also relevant sub-groups.

Priority actions:

2.1 Make available national experts for joint assessment of notified bodies (Member States)

2.2 Consider how notified bodies can perform conformity assessment activities in COVID-19 circumstances (Commission, MDCG)

2.3 Member State discussion on increasing notified body capacity (MDCG, MDCG NBO WG, MDCG IVD WG, Commission)

Set B – high priority actions

This section describes actions that are not essential to allow manufacturers to place devices on the market, but which would greatly facilitate the work of the involved actors. They include designation of EU reference laboratories, common specifications, guidance on a number of topics and standards.

3. EU reference laboratories

The IVDR stipulates that the Commission may designate a new type of independent scientific body, the EU reference laboratories. EU reference laboratories have never previously been set up in the field of IVDs. These laboratories, if designated, will carry out additional tests on class D devices that fall in their scope of designation. They will in particular verify the performance of class D devices and compliance with any common specifications before the device is placed on the market. Furthermore, they will carry out tests on samples or batches of CE-marked class D devices before they are placed on the market. The EU reference laboratories will also make their expertise available for a range of advisory functions. Therefore their establishment is important for high-level, consistent assessment of class D devices in the Union.

The IVDR enables designation of EU reference laboratories on 25 November 2020 or later. The Regulation does not make it mandatory to have an EU reference laboratory for any kind of class D device – it is at the discretion of the Commission to

[7] According to data provided by notified bodies, only 31 IVDR certificates had been issued as of September 2021.

designate them. If no EU reference laboratory is designated for a particular device, those requirements are not applicable.

Two implementing acts prescribed by Article 100(8) of the IVDR, on tasks and criteria and on fees to be levied by the EU reference laboratories, must be adopted with the application date not earlier than 25 November 2020. As it is the Member States who will nominate the laboratories, the Commission will continue to discuss any practical issues related to EU reference laboratory establishment with the Member States. The Commission will then issue a call for application to Member States (and the Joint Research Centre) to nominate candidate laboratories. The call should be open for a sufficient length of time to allow candidate laboratories to prepare themselves for applications. To inform the assessment of the received applications, the Commission will gather information on the needed capacity of EU reference laboratories for their core functions of performance verification and batch testing. As fees will cover services to notified bodies and Member States, the possibility to make a Union contribution to cover the costs of other tasks should be investigated.

Priority actions:

3.1 Discussion with Member States on practical aspects related to EU reference laboratories (Commission, MDCG/MDCG IVD WG)

3.2. Adopt implementing acts on tasks and criteria and on fees to be levied by the EU reference laboratories (Commission, Committee on Medical Devices)

3.3 Carry out survey on needed capacity of EU reference laboratories (Commission)

3.4 Issue call for application to Member States and the Joint Research Centre (Commission)

3.5 Assess the applications and designate the EU reference laboratories (Commission)

3.6 Investigate a Union contribution for tasks that are not covered by fees (Commission)

4. Common specifications

Common specifications are legally binding requirements on certain elements of conformity assessment, adopted in the form of an implementing act. If the manufacturer does not comply with the common specifications, they must justify that they have adopted solutions that achieve at least an equivalent level of safety and performance of the device. While the adoption of common specifications is optional according to Article 9 of the IVDR, common specifications create consistently high benchmarks for device documentation and performance, and provide certainty for the market actors. Compliance with common specifications allows manufacturers to claim presumption of conformity with the requirements of the IVDR covered by the common specifications. Notified bodies and EU reference laboratories will assess

the device against common specifications and their existence exempts the devices covered from the additional step of expert panel consultation.

An extensive set of common technical specifications exists under Directive 98/79/EC (Decision 2002/364/EC). In addition, new common specifications for class D devices are being developed in the IVD sub-group of the MDCG according to a roadmap endorsed by that group. The group has generally agreed that the common technical specifications under the Directive should be transposed to become common specifications IVDR without major revision. Minor editorial revision may be necessary. Any newly developed common specifications should be added to this text, provided that there is sufficient agreement on their content. Three such new sets of common specifications could be added in this first round, as mature drafts are available (concerning Kidd and Duffy blood grouping, Chagas and syphilis, and cytomegalovirus/Epstein-Barr virus devices). Other CS, for which no drafts are currently available, would be developed and adopted in later rounds.

Priority actions:

4.1 Propose the sets of CS will form part of the first adoption round (Commission)

4.2 Agree on the text to be adopted as part of the first round (MDCG IVD WG, MDCG, Commission)

4.3. Adopt the first implementing act containing common specifications (Commission, Committee on Medical Devices)

5. Guidance for notified bodies

A large amount of guidance for notified bodies on aspects that are common for the MDR and IVDR has already been published or is in preparation under the MDR joint implementation plan.

This section considers key guidance for notified bodies that is specific to the IVD sector.

Guidance on classification of devices has already been produced (MDCG 2020-16).

Guidance on notified body designation codes[8] defining the scope of the notified bodies' activity will contribute to harmonised use of the codes especially for the allocation of resources to conformity assessment activities. This guidance will aim to explain the different level of codes and how they should be used, including the use of conditions.

[8] These codes are laid down in Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council, OJ L 309, 24.11.2017, p. 7–17.

A further important guidance element relates to the interaction between the manufacturer, the notified body and the newly established EU reference laboratories as regards batch testing. It aims to clarify the responsibilities of each actor as laid down in the IVDR and the practicalities of the interaction.

To help ensure consistent application of transitional provisions, and in particular application of Article 110(3), clarification would be beneficial as to which changes to a device should be considered as a "significant change in design or a significant change in the intended purpose", as referred to in that Article. Guidance on this topic should also include operational flowcharts to facilitate harmonised judgement of the significance of changes.

Furthermore, regarding Article 110(3) second subparagraph, notified bodies, manufacturers as well as designating authorities urgently need clarity on the meaning of "appropriate surveillance in respect of all applicable requirements relating to the devices it has certified". In this context, a guidance document should specify the activities to be performed by notified bodies as part of the appropriate surveillance and also cover requirements concerning certain manufacturers' obligations, especially in respect to their quality management system.

Priority actions:

5.1 Complete and endorse guidance on notified body designation codes. (MDCG NBO WG, MDCG IVD WG, Commission, MDCG)

5.2 Complete and endorse guidance on batch testing for notified bodies (MDCG NBO WG, MDCG IVD WG, Commission, MDCG)

5.3 Develop guidance on significant changes as referred to in Article 110(3) of IVDR (MDCG NBO WG, MDCG IVD WG, Commission, MDCG)

5.4 Develop guidance on appropriate surveillance as referred to in Article 110(3) of the IVDR (MDCG NBO WG, MDCG IVD WG, Commission, MDCG)

6. Performance evaluation and expert panels

The IVDR significantly strengthens requirements on **clinical evidence** of devices. For example, it specifies three elements of performance evaluation: scientific validity, analytical performance and clinical performance, and lays down detailed requirements on how these shall be demonstrated. Documentation including a performance evaluation plan, performance evaluation report and a post-market performance follow-up plan is required. To ensure a consistently high level of patient safety and public health, there should be a common approach for applying the strengthened provisions on clinical evidence. Therefore guidance in this area is a high priority.

The performance of class D devices is to be verified by an EU reference laboratory, which are addressed in point (b). For very novel high-risk devices, as an additional element of conformity assessment, the notified body must consult the expert panels on the performance evaluation report of the manufacturer. This is foreseen "*where*

no common specifications are available for class D devices and where it is also the first certification for that type of device". To clarify in which cases the notified body needs to involve the expert panel, it is necessary to provide guidance on what constitutes a "first certification for that type of device" for the purposes of this requirement. Moreover, it is necessary to clarify how a notified body may check whether or not it is performing the first certification and what happens to other certifications of that device type while the expert panel is giving its views.

Article 29 of the IVDR lays down a requirement for a new document for class C and class D devices – the summary of safety and performance. It is to be assessed by the notified body and to be made publicly available on Eudamed. Notably it must contain a summary of performance evaluation and relevant information on post-market performance follow-up, in a way that is clear to the intended user and, if relevant, to the patient. This document is important from the point of view of transparency, as it is intended to present key information on performance of the device to the public in an accessible way. As it is a new requirement, guidance on how to structure the summary of safety and performance should be developed. This should build on the work already carried out on the equivalent summary of safety and clinical performance for medical devices in the MDCG CIE WG.

The IVDR lays down for the first time EU-level requirements regarding application for or notification of certain performance studies, through Eudamed when it is functional. While Eudamed is in development, a single EU-wide template for this, specifying a common set of elements to be provided and a common format to present them, would be of high added value to streamline the authorisation or notification process. It should be based on the analogous template for clinical investigations under the MDR and should cover performance study application for certain high-risk performance studies (IVDR Art. 58(1 & 2)), PMPF study notification (IVDR Art. 70(1)), performance study notification involving companion diagnostics using left-over samples only (IVDR Art. 58(2)), or other performance study application/notification - national application (Art. 57).

Priority actions:

6.1 Complete and endorse guidance on clinical evidence for IVDs. (MDCG IVD WG, MDCG CIE WG, MDCG)

6.2 Develop and endorse a clarification on what constitutes a "type of device" and on the process to be followed by notified bodies in context of views of the expert panel. (MDCG NBO WG, MDCG IVD WG, MDCG)

6.3 Develop and endorse template for summary of safety and performance (MDCG IVD WG, MDCG CIE WG, MDCG)

6.4 Develop and endorse template for application/notification of performance studies. (MDCG CIE WG, MDCG IVD WG, MDCG)

7. Standards

Availability of harmonised European standards cited in the *Official Journal of the European Union* (OJEU) to confer presumption of conformity would support

compliance with the requirements of the IVDR for manufacturers. For that, the Commission must request the relevant European standardisation organisations (CEN and Cenelec) to revise the existing standards and to develop new standards, and subsequently publish in the OJEU lists of references of harmonised standards under the MDR and the IVDR, to be continuously updated and enlarged on a regular basis.

Priority actions:

7.1 Adopt the implementing act on the MDR/IVDR standardisation request (Commission, Committee on Standards) and accept it (CEN/Cenelec)

7.2 Adopt the implementing acts on the publication in the OJEU of references of harmonised European standards in support of the IVDR requirements (Commission)

8. Companion diagnostics

Companion diagnostics are defined in the IVDR as devices essential for the safe and effective use of a corresponding medicinal product, to identify, before and/or during treatment, either patients who are most likely to benefit from that medicinal product or patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. While they represent a small fraction of the IVD market, they are important for correct use of the corresponding medicinal product and for access of patients to tailored and therefore more effective treatment. Their development is inherently linked to that of the medicinal product. Guidance on companion diagnostics is needed in view of the strengthened requirements on performance evaluation and a new requirement for the notified body to consult a medicinal product authority or the European Medicines Agency (EMA) regarding the suitability of the device in relation to the medicinal product concerned. As the first priority, to allow these devices to complete the conformity assessment, a basic process for the consultation should be put in place. This should include the procedural elements as well as basic aspects of the content of the consultation.

Priority actions:

8.1 Regarding the consultation of medicinal product authorities, accompany the work of the EMA and stakeholders, notably on procedural elements (MDCG IVD WG, medicinal product authorities, EMA)

9. In-house devices

The IVDR, compared to the IVDD, significantly strengthens the requirements for devices developed and used within the same health institution according to Article 5(5), known in-house devices. Regulation (EU) 2022/112 deferred the application of most of the conditions to be met by health institutions making in-house devices until 26 May 2024. The requirement for the justification that there is no equivalent CE marked device available to meet the target patient group's specific needs is

proposed to be deferred even further, until 26 May 2028. These devices were very important in the response to the COVID-19 pandemic, especially in its beginning. Laboratory professionals have raised a number of questions about practical application of these new provisions. Common understanding of the requirements is important for routine operation of hospital laboratories, for the national competent authorities who will oversee the compliance of the laboratories with the legal requirements, as well as to enable laboratories to respond effectively in the context of a health crisis.

Therefore, it would be beneficial to develop relevant guidance already now. As the MDR contains similar provisions, this matter should be tackled in collaboration between the IVD WG and relevant medical device competent authorities.

Priority actions:

9.1 Develop guidance explaining the provisions on in-house devices (MDCG IVD WG, MDCG MS WG)

10. Legacy devices

Article 110(3) of the IVDR states that, for devices placed on the market prior to 26 May 2022 and for those that can lawfully be placed on the market according to the transitional provisions ('legacy devices'), "*the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in the second and third subparagraphs of this paragraph, instead of the corresponding requirements in Directive 98/79/EC*". As the wording of this paragraph is rather general, it is useful to clarify the specific IVDR requirements that are applicable or not applicable to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in this context, as it has been done for Regulation 2017/745 by guidance MDCG 2021-25. Due to the differences between IVDs and medical devices (e.g. different classification systems), as well as the different transitional provisions, the existing guidance document MDCG 2021-25 cannot be applied to IVDs.

Priority actions:

10.1 Develop and endorse a guidance document on the application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC (MDCG IVD WG, MDCG NBO WG, MDCG PMSV WG, MDCG MS WG, MDCG)

11. Eudamed

Eudamed will not be fully functional by 26 May 2022, and the transitional provisions of Article 113 (3)(f) IVDR apply, therefore the use of the system will not be mandatory or enforceable until the date corresponding to six months after the date of

publication of the notice referred to in Article 34(3) MDR. Therefore, it would be beneficial to have guidance on harmonised administrative practices and alternative technical solutions for the exchange of information until EUDAMED becomes fully functional. The guidance should enable Member States and other relevant parties to meet their obligations under the IVDR effectively, while minimizing any potential additional burden on the parties concerned. It should address in particular cases where the exchange of information would be difficult, or even not possible, to achieve in absence of guidance.Priority actions:

11.1 Develop and endorse IVDR-specific guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (MDCG Eudamed WG, MDCG IVD WG, MDCG)

III. Beyond 26 May 2022

The short term priorities set out above should be seen in the context of continuous prioritisation by all actors involved beyond 26 May 2022 in the frame of a **strategic plan for medium- and longer-term actions** that should be established to provide for the most optimal implementation of the legal framework on IVDs within the limits of available resources.

Further guidance is envisaged in the areas of performance studies, summary of safety and performance, in-house devices, companion diagnostics and qualification of devices used in clinical trials of medicinal products.

Commission services are committed to keep MDCG regularly updated on the overall progress towards full functionality of Eudamed.

Furthermore, cooperation and collaboration on **market surveillance and vigilance** is key to ensure that devices on the market are safe. More clarity is needed as regards certain aspects of the application of these requirements.

Engaging in this type of prioritisation exercise in the medium and long term will require a more strategic role of the MDCG with increased coordination with and between MDCG sub-groups in a transparent manner and a common frame for coordinating information between all actors. Further reflections on the **most optimal governance function**, with the view to optimise resources and expertise has been initiated by the MDCG.

* * * *

Annex

Summary of actions

Set A – essential actions

No	Topic	Action	Timeline	Status
1	**Contingency planning and monitoring**			
1.1		MDCG-level forum for Member States to discuss risks to product availability and work on proposed solutions	Regular, from Q4 2020	Ongoing
1.2		Market monitoring exercise (including quantitative information on stakeholder readiness, barriers to designation and to certification of devices)	Regular, from Q4 2020	Ongoing
1.3		Analyse the IVDR in context of hypothetical scenarios of an urgent response to a health crisis	Q2 2022	Ongoing
2	**Availability of notified bodies**			
2.1		MS to provide experts for joint assessments	Continuous	Ongoing
2.2		Consider how notified bodies can perform conformity assessment activities in COVID-19 circumstances	Until the end of the pandemic	Notice published Monitoring ongoing
2.3		MS discussion on increasing notified body capacity	Continuous	Ongoing

Set B – high priority actions

No	Topic	Action	Timeline	Status
3	**EURLs**			
3.1		Discussion with Member States on practical issues related to EU reference laboratories	Continuous	Ongoing
3.2		Implementing acts on tasks and criteria and on fees	Q2 2022	In final stages of adoption
3.3		Survey on expected EURL demand	Q1 2021	Completed
3.4		Issue call for application	Q2 2022	Draft in revision
3.5		Complete assessment and designate the EURLs	Q1 2023	Not yet started
3.6		Investigate Union contribution for tasks not covered by fees	Q3-4 2021	Ongoing
4	**Common specifications**			
4.1		Propose which sets of CS will form part of the first adoption round	Q1 2021	Completed
4.2		Discuss the text to be adopted in	Q1-2 2021	Completed

		the first adoption round		
4.3		Adoption procedure of the first implementing act on common specifications	Q2 2022	Ongoing
5	**Guidance for notified bodies**			
5.1		Explanatory note on notified body designation codes	Q2 2021	Completed
5.2		Guidance for notified bodies on batch testing	Q4 2021	Completed
5.3		Guidance on significant changes referred to in Article 110(3)	Q2 2022	Ongoing
5.4		Guidance on “appropriate surveillance” according to Article 110 (3) IVDR	Q3 2022	In preparation
6	**Performance evaluation and expert panels**			
6.1		Guidance on clinical evidence for IVDs	Q1 2022	Completed
6.2		Clarification on what constitutes a “type of device” and on process to be followed by NBs in context of views of expert panel	Q2 2021	Completed
6.3		Template for summary of safety and performance	Q2 2022	In preparation for endorsement
6.4		Template for application/notification for performance studies	Q2 2022	Draft in preparation
7	**Standards**			
7.1		Adopt the implementing act on the MDR/IVDR standardisation request	Q2 2021	Adopted by COM and accepted by CEN/Cenelec
7.2		Adopt the implementing act on the publication in the OJEU of references of harmonised European standards	Q2 2021	1st publication done Q2 2021, 2nd publication done Q1 2022, 3rd publication foreseen for Q2 2022
8	**Companion diagnostics**			
8.1		Regarding the consultation of medicinal product authorities, accompany the work of the EMA and stakeholders, notably on procedural elements	Q1 2022	Ongoing
9	**In-house devices**			
9.1		Guidance on in-house devices	Q2 2022	Processing outcome of stakeholder

				consultation
10	**Legacy devices**			
10.1		Guidance on application of IVDR requirements to legacy devices and those placed on the market before 26 May 2022	Q2 2022	Consultation ongoing
11	**Eudamed**			
11.1		IVDR-specific guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional	Q2 2022	Consultation ongoing