CAMD Implementation Taskforce

Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap

Overview and proposed terms of reference

The Competent Authorities for Medical Devices (CAMD) Executive Group recommended the establishment of an MDR/IVDR implementation taskforce to facilitate collaboration and cooperation within the medical devices network during the implementation phase of the new Regulations. As part of the implementation phase a consistent and harmonised approach in interpretation of the regulations across the network is fundamental to ensure consistency in the application of these regulations. The objective is to implement an effective, robust, predictable and secure regulatory system and ensuring better protection for public health in the medical devices sector. The taskforce is not intended to replace or prevent any national-specific implementation planning or activity that a Competent Authority wishes to conduct.

The Phase I objectives of the taskforce were to:

- help identify key issues that require clarification between authorities to ensure a uniform interpretation of the requirements and expectations of key provisions;
- help identify key issues that require clarification for all stakeholder groups to ensure consistency in the application of the regulations;
- help identify the need for guidance for stakeholder groups in terms of the expectations and interpretations of the relevant provisions; and
- optimise resources, minimise duplication of work across the network, cooperate and collaborate in the implementation phase in reaching consensus, drafting guidance and developing processes between authorities and stakeholders.

In delivering on the taskforce objectives a number of workshops were held at the CAMD meetings in Amsterdam in June 2016 and in Bratislava in October 2016. These workshops helped identify the key implementation challenges for each technical work stream identified. As an output from that exercise, the CAMD implementation taskforce has developed a priority listing to help identify the key issues to be addressed and a recommendation on where it may best be addressed as part of the implementation phase. Following the workshops these priorities were circulated for initial endorsement by the whole CAMD network, and the Working Group Chairs, which will be responsible for meeting several of these priorities.

Following CAMD endorsement, the taskforce, in collaboration with the Commission, initiated a formal engagement exercise with European stakeholders with the ultimate aim of using the priorities as the basis for the development of a single European ‘roadmap’ for implementation. The feedback from stakeholders has been assessed by the Taskforce, and where considered appropriate, amendments to the priorities have been made accordingly. This version of the priorities has therefore accounted for Stakeholders’ views and feedback.

Following publication of the roadmap, the Taskforce intends to first engage with all recommended parties to identify the project plan and deliverables of each priority and then to continue monitoring the progress of implementation work.

Priorities for implementation of MDR & IVDR

This list of actions are priorities for the European network in facilitating an effective implementation of the MDR and IVDR. Input for this list was provided by participants of the CAMD meeting in Amsterdam and Bratislava and through the feedback from European Stakeholders. In this priority list seven technical areas/work streams for implementation are defined. In addition, some over-arching/cross cutting issues are included

In the following table, the recommendations identifying where the work may best fit are made. The majority of priorities related to IVDs have been captured within the technical areas listed above, however the IVD-specific workstream allows issues specific to IVDs to be addressed.

A priority rating has been assigned in consultation with the working group chairs. The priority setting takes into consideration work already in train by the Commission and other partners. While a generic priority of high, medium and low is assigned to the work items, these priorities will become more defined and specific by the individual working groups tasked with each activity. It is in fact proposed that a defined project plan is developed by each working group specifying the timeframes and key milestones to deliver on the implementation plan.

Throughout the table, many of the deliverables listed are guidance documents. It is important to note that although the MDR and IVDR has specified implementing acts to define how certain provisions are to be applied, it is envisaged that additional guidance and information might be needed in advance. What form this guidance will take and how it will be issued will be dependent on future discussions on specific topics e.g. will an update of current MEDDEV be possible in time.

1. Clinical Evaluation & Clinical Investigation (MD); Performance Evaluation & Performance Studies (IVD)

	Activity	Recommended responsible parties/owners	Priority level
1.1	**Clinical evaluation work package** • Guidance on equivalence, well established technologies, clinical evidence • Gap analysis of MEDDEV 2.7/1 • Contribution to relevant Implementing Acts (IA) • Work on interface between various documents/reports e.g. CER, SSCP, PSUR. • Contribution to guidance on performance evaluation and clinical evidence for IVDs	• CIE WG • IVD WG	High
1.2	**Template document development (see also 4.4)** • Summary of Safety and Clinical Performance (SSCP) [MD] • Summary of Safety and Performance [IVD] • Clinical Evaluation Assessment Report (MD) • Performance evaluation plan and performance evaluation report (IVD) • Clinical Investigation application form (MD) • CI Assessment Report (MD) • Performance study Application Form (IVD) • Performance Study Report (IVD) • SAE/device deficiency reports and timelines (MD and IVD) • PMCF plan and PMCF report (MD) • PMPF plan and PMPF report (IVD)	• CIE WG • IVD WG • NBOG • EUDAMED WG	Medium – High
1.3	**Clinical investigation (MD) and (clinical) performance study (IVD) assessment** • Identification of key principles/considerations of CI (MD) and PS (IVD) assessment • Development of training materials/methods/mentoring schemes • Development of coordinated assessment procedure for MD and IVD	• CIE WG • IVD WG	Medium

	Activity	Recommended responsible parties/owners	Priority level
1.4	**Common specifications** • Template/headers for common specifications (CS) – guidance on types of detail required/expected • Analysis of work undertaken in other regulatory jurisdictions and transferability • Interaction/alignment with harmonised standards • Identification and prioritisation of devices requiring specifications • Transfer of current Common Technical Specifications (CTS) for IVDs to CS under the IVDR. • Identification of and prioritisation of IVDs requiring CS and for which currently no CTS exist • Applicability to existing products • Interaction with international standards	• CIE WG • IVD WG • NET WG • NB-MED • NBOG/Vigilance WG • COM • JAMS	Medium
1.5	**Companion diagnostics – guidance for their assessment, and use in performance studies** • Development of template for the application dossiers and guidance incorporating medicinal products (MP) consultation	• IVD WG • CIE WG • EMA	Low

2. Scope & Classification

	Activity	Recommended responsible parties/owners	Priority level
2.1	**Classification guidance for IVDs around classification rules and scope, giving practical examples**	• IVD WG • C&B WG • Software WG	High
2.2	**Information and guidance on classification for MDs (changes on classification rules)** • Information to highlight changes to classification rules • Guidance on new classification rules/changes to existing rules e.g. MEDDEV 2.4/1 update/addendum • Software classification guidance (to liaise with workstream 2.1 IVD Classification)	• C&B WG • Software WG • NET WG • IVD WG	Medium
2.3	**Common specifications for annex XVI products for MDs**	• COM • MDCG • NBOG	High
2.4	**Implementing act on reprocessing SUDs for MDs**	• COM • MDCG	Medium
2.5	**Guidance for combination products and companion diagnostics (CDx) around appropriate level of interaction with relevant authorities (ref: 3.4)**	• C&B WG • IVD WG • (HMA-CAMD borderline WG, EMA, medicines CAs, tissues & cells CAs, EDQM) • NBOG	Low

3. Notified Bodies & Conformity Assessment

	Activity	Recommended responsible parties/owners	Priority level
3.1	**Implementing act(s) with list(s) of codes and corresponding types of devices to describe the scope of the designation**	• JACG • NBOG • IVD WG	High
3.2	**Guidance to be issued on designation process for joint assessments under the new regulations**	• JACG • NBOG • IVD WG	High
3.3	**Capacity and expertise of assessors – training based on a gap analysis**	• JACG • IVD WG	High
3.4	**Guidance on different routes for conformity assessment** • What is a significant change? • What is expected in a technical review? • Communication channels between Notified Bodies (NBs) and Competent Authorities (CAs) on CDx and other consultations (see also 2.5)	• NBOG • NB Med • IVDWG	Medium
3.5	**Conformity assessment – clarity over procedures for notified bodies** • The meaning of technical documentation assessments on a representative sampling basis • Clear guidance on the differences between IVD Class B and C conformity assessment procedures	• NBOG • IVD WG • JACG • MDCG • Input from CIE	High Medium
3.6	**DAs review of NB assessments (clinical and technical included)** • Review of NB assessment of technical and clinical evaluation, including how clinical & scientific expertise will be sourced • Planning/sampling of notified body assessments	• JACG • NBOG • CIE WG • IVD WG	Medium

4. Post-Market Surveillance & Vigilance for both MD and IVD

	Activity	Recommended responsible parties	Priority level
4.1	**Define trend, signal detection and signal management processes** • This will be very important and will need to be researched and developed to know how to inform Eudamed development • Reporting requirements when issues are detected outside the EU – clarify process	• Vigilance WG • Input from COM • IVD WG	Medium
4.2	**Guidance on requirements for vigilance reporting** • Identify gaps between the current MEDDEV and the MDR and IVDR (issue as Interim guidance via CAMD website with a view to updating a MEDDEV in due course) • Details on how vigilance should be reviewed in clinical evaluation for MD and performance evaluation for IVD as well as the required detail of the investigations undertaken • Focus on new MIR form, what vigilance looks like for member states, flag areas that are law rather than guidance and where MEDDEV needs to be updated to reflect the new Regulations	• Vigilance WG • CIE WG • IVD WG	High
4.3	**Develop and agree terminology for MD/IVD Adverse Nomenclature and patient harm** • MD and IVD AE nomenclature to be defined • Identification of Patient harm nomenclature including problem, cause investigation etc	• Work already in progress at IMDRF – terminology already underway, completion expected by 2018	High
4.4	**Development of revised templates (MIR, FSN, FSCA, Trend, PSR, Vigilance exchange forms, and new forms for PSURs + summary of safety & performance and PMCF/PMPF alignment)** (with Eudamed development too) [ref workstream 1.2 also]	• Vigilance WG • Eudamed Ad Hoc WGs • IVDWG	Medium

5. Eudamed & UDI

	Activity	Recommended responsible parties	Priority level
5.1	**Uniform input into the design/development of a functioning Eudamed** • Simple registration processes for devices, manufacturers and AR • Proper interoperability with national databank systems • Clear and early instruction to stakeholders on how to interact with the system (provide clear timelines to stakeholders)	• COM • Supported by the Eudamed Steering Committee and *ad hoc* working groups	High
5.2	**Guidelines for manufacturer on UDI assignments** (e.g. when is a new UDI or Basic UDI-DI necessary?) • Criteria for new UDI-DI • Criteria for a new Basic UDI-DI • Clarification on catalogue numbers and association with UDI-DI • Alignment with International systems • Identification of exceptional cases e.g. special device groups like contact lenses • Guidance on UDI requirements for certificates, summary of safety and performance, PSURS, on vigilance reports, FSA, FSN, etc. • UDI application for software • Parallel traders and OBL	• UDI taskforce within the UDI WG	High Medium
5.3	**Guidelines on UDI carriers, UDI marking** • Which are the preferred commonly used barcodes (which 2D Barcodes, How to deal with RFID?) • Where to put the Barcode on the device or on parts of a device system? • How to deal with the serialisation requirements • How to ensure readability of the Barcode on devices with direct part marking • Where to put the UDI carrier in case of implants? • Two UDIs from two different issuing entities on one label?	• UDI taskforce within the UDI WG • Co-ownership with industry	High

	Activity	Recommended responsible parties	Priority level
	• How to control UDI labelling inside of the Manufacturer's Quality Management System (QMS)?		
5.4	**Guidelines/Clarification on registration and UDI in specific cases (Parallel trades, OBL, Reprocessors etc.)** • Roles & responsibilities across various actors and clarification of Eudamed reporting channels. Clarification on obligations of parallel traders/Own Brand Labellers (OBL)/reprocessors/manufacturers of aesthetic MDs with respect to compliance with UDI requirements	• Eudamed ad hoc working groups with the UDI WGs [stakeholder mapping will be similar to those undertaken in the overarching priorities]	Medium
5.5	**Guidelines for CA on how to perform validation of registration data** • Clarification and guidance on how to validate the information provided by the manufacturer or Economic Operator for registration purposes • Development of data analytics for Eudamed for market surveillance purposes and training • Guidance on harmonising registration process in absence of Eudamed	• Eudamed Steering group • Links to all working groups	Medium
5.6	**Importer/distributor certificates and SUD conformity assessment** • Clarification on how certificates issued according to Articles 16 (4) and 17 (5) MDR/Article 16 (4) IVDR will be captured by designation and monitoring activities	• NBOG • Eudamed • NB associations • IVD WG	Medium

6. Market Surveillance

	Activity	Recommended responsible parties	Priority level
6.1	**Cooperation between NCAs** • Identification of mechanisms to promote coordination and cooperation on market surveillance activities • Development of protocols and procedures for coordination and cooperation on EU market surveillance issues • Development of best practices for market surveillance planning Develop publicly-available information about the rationale and general risk-based principles of proactive MS.	• The Joint Action on Market Surveillance (JAMS), project part funded by The Health Programme, is specifically addressing this area and is working to a defined set of deliverables regarding coordination and communication of activities on market surveillance • Close liaison to be maintained between COEN and JAMS • Dependent on clarification of the role of MDCG.	Medium
6.2	**Production of general, high-level CAMD guidance/infographics for economic operators (EO) clarifying expectations** around: • EO obligations • Responsible person • Liability • Interaction with Eudamed • Registration requirements This should be written in a suitable style without too much technical detail- the intention should be to flag the key changes and spark EOs to initiate action	• COEN • Input from IVD WG, Eudamed WG, Vigilance WG • Avoid duplication by working closely with other WGs to identify scope of guidance and avoid duplication	Medium

	Activity	Recommended responsible parties	Priority level
6.3	**NCA market surveillance obligations in accordance with Article 93 (MDR) and Article 88 (IVDR)** • Identify areas and candidates for sharing of expertise and best practise regarding manufacturer inspections • Identification and development of mechanisms to ensure market surveillance activities are harmonised. Collaborative planning and optimisation of resources where possible • Mapping specialist expertise across the system • Identify and collect the national policies on planning inspections • Identify training needs and available expertise within the authority network	• Work currently underway within the JAMS project, WP4 (manufacturer inspections) and WP5 (clinical process and resource development) • Liaise with COEN and CAMD to ensure continued awareness and communication of deliverables	Medium
6.4	**Understanding of transitional arrangements between RAMS (Regulation on Accreditation and Market Surveillance - New Legislative Framework) and MDR/IVDR, as well as 'gap analysis' of major changes** • Identify specific activities and processes that fall under Regulation 765/2008 and any impact from transitional timeframes • Identification of existing guidance for manufacturers and carry out MDR/IVDR needs analysis	• COEN WG	Medium
6.5	**Definition of Market Surveillance activities** • Mapping of market surveillance activities • Development of tools and guidance on proportionate measures to address • Procedural guidance on use of safeguard clause • Development of mechanism for contribution of NBs to market surveillance activities • Define process for reporting on activities prior to Eudamed • Guidance on how clinical information should be used as part of market surveillance, including review of CER/PER and CPSR (plus PMCF/PMPF reports)	• COEN WG • With input from NBOG, Vigilance and CIE, IVD WG, and other WGs	Medium

7. IVD-specific Issues

	Activity	Recommended responsible parties	Priority level
7.1	**Reference Laboratories** • Information to support the prompt designation of EU reference labs • Guidance on how Class D IVDs can be assessed in the absence of Common Specifications	• COM • IVD WG • MDCG	High
	Performance Evaluation and Performance Studies - Performance studies template documentation development - Principles, training and coordination of performance studies - Guidance for assessment of CDx and use in performance studies	• Covered under 1.Clinical workstream under CIE WG and co-development with IVD WG	
	Scope and Classification - Classification guidance - Guidance around appropriate level of interaction on combination products with relevant authorities	• Covered under 2. Scope & Classification workstream under IVD WG with input from C&B WG, software WG, NET WG	
	Notified Bodies - Implementing acts and list of codes - Designation process - Capacity and expertise of assessors - Clarity over conformity assessment procedures - DA's review of NB assessments	• Covered under 3. Notified Body & conformity assessment workstream under JACG, NBOG, IVDWG, MDCG, CIEWG	
	Post market surveillance and Vigilance - Develop and agree terminology for IVD problem, cause investigation, patient harm - Guidance on requirements for vigilance reporting	• Covered under 4. Post market surveillance and vigilance workstream under Vigilance WG with co-development from IVD WG, CIE WG	

	Eudamed and UDI - Input into development for IVD data sets	• Covered under 5. Eudamed and UDI workstream lead by COM, with input from IVD WG	
	Market Surveillance - Production of high level CAMD guidance for economic operators - Development of tools for market surveillance and processes for reporting	• Covered under 6. Market surveillance workstream input from IVD WG into JAMS and COEN	
	Cross Cutting Issues - Transition provisions, resourcing, MDCG role	• Covered under 8 Overarching and cross cutting priorities with input from IVD WG and all WGs	

NB: The majority of priorities related to IVDs have been captured within other clusters, however the IVD-specific cluster allows issues specific to IVDs to be addressed.

8. Over-arching & Cross-cutting Priorities

	Activity	Recommended responsible parties	Priority level
8.1	**Transitional problems & uncertainties, and risks to continued supply of safe devices** In order to tackle the many uncertainties about the application of provisions in the transition periods, a comprehensive exercise must take place to ensure common interpretation among authorities. Issues addressed should include: Pre-Date of application (DoA) • How products can comply in the transition periods (according to art 120(5) MDR/110(5) IVDR • Legal status of CI/PS being conducted within the transition period. What happens if trial begins according to Directives before DoA but finishes after? • Legal enforcement powers during transition period • Obligations of economic operators • How this works in practice without Eudamed, and expectations on authorities • How do statutory reporting deadlines apply in absence of Eudamed (e.g. 15 day deadlines)? Post-DoA • Devices being placed on the market for a limited period after the transition period under a certificate issued in line with the Directives (including aspects of NB changes and reclassification of devices) • Eudamed derogations around registration, reporting and clinical investigations Development of contingencies & scenario planning around • Availability of NBs designated under MDR/IVDR (in conjunction with NB no.2) • Availability of authorised representatives, and other market actors with capability of fulfilling the legal requirements • Risks of increased regulatory burden leading to supply issues of low-volume products, IVDs in particular	• Transitional Measures Taskforce has been established • Recommended that legal input is included • Liaison with stakeholders to ensure all issues identified National Competent Authorities (NCAs) MDCG CAMD	High

	Activity	Recommended responsible parties	Priority level
8.2	**Stakeholder engagement** • Central coordination of information during implementation to ensure engagement with all affected stakeholders • Consider a mechanism where challenges of the regulation are discussed with stakeholders and any outputs in terms of a guidance/information are identified, centrally coordinated and communicated to the stakeholders involved as a harmonised approach (e.g transitional provisions). This also includes identifying all new stakeholders and the best mechanisms to engage them (new stakeholders who we are not used to talking to – Annex XVI, new distributors and importers) (Longer term could feed into a training work package)	• Implementation Task Force, in partnership with the Commission and Working Group Chairs • NCA-Industry collaboration to assist with engaging new stakeholders	Ongoing
8.3	**Resources requirements** • Identification of issues with implementation due to lack of expertise and resource • Identification of areas for peer training to help address resource and expertise issues	• Competent Authorities	High
8.4	**Defining Responsibilities** • Responsibility for conformity assessment of parallel importers and reprocessing of SUDs	• MDCG	High
8.5	**Contributing to ensure Eudamed is fit for purpose for audit and from go-live**	• All Competent Authorities to liaise through Eudamed Steering Committee • Eudamed ad hoc groups • UDI WG • COM	2020
8.6	**Clarify MDCG role in the governance of the regulations** • With regard to article 105 and the Tasks of the MDCG, it is expected that guidance will be published outlining the roles and responsibilities of the MDCG in this regard	• COM • MDCG	High

	Activity	Recommended responsible parties	Priority level
8.7	**Expert Panels and Expert laboratories** • Governance structure to be defined including information to support the prompt designation of EU expert panels and expert labs	• COM • MDCG	high