MDCG 2019-6

Questions and answers:

Requirements relating to notified bodies

June 2019

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Introduction

This document presents questions and answers on requirements relating to notified bodies under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). The issues covered by this document have been identified in the context of joint assessments, and the document may be updated from time to time as new issues are identified.

I. ORGANISATIONAL AND GENERAL REQUIREMENTS

I.1. Are CABs obliged to follow guidance endorsed by the Medical Devices Coordination Group (MDCG)?

Guidance documents are by definition not compulsory. However, all guidance documents endorsed by the MDCG reflect the interpretation of the EU law jointly agreed by the authorities which are in charge of interpreting and applying the EU law. Hence notified bodies should be encouraged to apply these guidance documents (also taking into consideration Section 1.6.2 of Annex VII to the MDR/IVDR[1]). Furthermore, it is to be noticed that the European Court of Justice often refers to guidance documents when developing its rulings. Hence Notified Bodies have an interest, also in terms of liability risk, to follow that guidance.

I.2. What is the meaning of “legal personality” under Section 1.1.1 of Annex VII to the MDR/IVDR?

The CAB needs to have legal personality, meaning that it has to exist as a legal entity. To that end, it must be registered as legal entity, also called "legal person". The wording of the MDR/IVDR does not exclude that only a part of a legal entity undertakes conformity assessment activities in the field of medical devices. In this case, where the CAB is part of a wider legal entity, the documentation provided should be clear as to where the CAB sits within that legal entity. In case the entire legal entity is the CAB, the documentation to be provided refers to the legal entity as such. It is always this legal entity as such which is designated (and not its organisational part).

I.3. What is the meaning of “organisation” as described in 1.1.2 of Annex VII[2]?

The term of "organisation" as described in 1.1.2 refers to the whole organisation (e.g. corporate group) to which the CAB belongs including the CAB's legal entity. The concept of "organisation" should be based not only on ownership rights (e.g. shares), but also functional/hierarchical links, such as voting/management/other control rights. One typical example of organisation is a holding company owning different companies (i.e. separate legal entities), one of them being or containing the CAB.

[1] 1.6.2. The notified body shall take into consideration guidance and best practice documents.

[2] Unless specified otherwise, a reference to Annex VII means a reference to both Annex VII of the MDR and Annex VII of the IVDR.

I.4. Does the term “organisational structure” as per 1.1.5 refer only to hierarchical relationships?

If a notified body is part of a larger organisation, both hierarchical (i.e. mother and daughter companies of the CAB) and horizontal relationships (e.g. sister companies where there is a common mother company) between the notified body and other entities belonging to that organisation are covered by the term "organisational structure".

The organisational structure of the CAB will vary depending on the complexity of the legal entity and the organisation to which it belongs. For instance, in the case of holding companies, the CAB could provide a matricial organisational chart with dual reporting relationships (i.e. functional and managerial). In this case, hierarchical and reporting lines should be clear and should match the information provided in job descriptions for the activities related to the MDR/ IVDR certification.

I.5. Is a 3-year competitor clause for consultants covered in the MDR / IVDR requirements?

The MDR/IVDR does no longer define the timelines for clearance of consultants that were defined in Section 1.3b of Annex I to the Implementing Regulation (EU) 920/2013, except in case that the person worked for the same company or the group (Section 1.2.4 of Annex VII). However, the requirements under the Implementing Regulation (EU) 920/2013 on the management of impartiality for consultants are included in sections 1.2.2, and 1.2.3 (c), (d) and (e) of Annex VII. Therefore, it is expected that CABs will have similar measures in place under both regimes. It is essential that competitors, authorised representatives and suppliers are also included in the identification, analysis and resolution of potential conflicts of interests.

I.6. May CAB provide pre-certification services?

Pre-certification services are not allowed before an application is lodged by the manufacturer (e.g. review of clinical data or assessment of the quality management system aside from regulatory standards such as ISO 13485) and therefore these services have to take place under the scope of the application.

Every activity carried out once an application has been submitted will be considered part of the conformity assessment activities and therefore if the manufacturer withdraws its application after this process has started, the notified body has to inform the other notified bodies through Eudamed according to Article 53(2) of the MDR / 49(2) of the IVDR. Whenever these activities consist in providing solutions to the manufacturer, they fall under the definition of consultancy and therefore the notified body impartiality policy and procedure(s) will need to cover that these pre-certification activities could be seen as consultancy. The CAB has to implement in their policy and/or procedures how it prevents that pre-certification activities carried out as part of the conformity assessment activities are falling into consultancy.

Services provided by the CAB that could fall under the definition of conformity assessment activities are not allowed outside of an application as they would be regarded as consultancy (e.g. gap analysis, check of MDR/IVDR readiness, use of mock-up files produced instead of “real” TD assessments). Nevertheless, general

training activities that are not client specific and that relate to regulation of devices or to related standards are allowed.

I.7. Can the CAB accept applications prior to being notified?

No, applications under the MDR / IVDR cannot be accepted before the designation of the CAB became valid, i.e. the day after the notification is published in NANDO.

I.8. How are the conditions on remuneration to be assessed within the meaning of 1.2.5 of Annex VII?

The MDR/IVDR establishes that remuneration cannot depend on the results of the assessments. Both direct and indirect correlations between results of the assessments and remuneration are prohibited. Hence an individual examination is needed. Special care has to be applied with regard to bonuses. Bonuses on the basis of general objectives, even when not directly linked to the result of the individual conformity assessments, might still be problematic if they indirectly correlate to the average result of assessments. In the context of a joint-assessment, sampling of contracts or agreements covering remuneration (sheets) should take place. The sampling should cover different grades of influence, e.g. project handlers, final reviewers/decision makers, or head of the CAB / medical devices' certification.

I.9. Are declarations of absence of conflict of interests sufficient to ensure compliance with legal requirements for impartiality?

No, declarations are not sufficient in isolation to ensure compliance. CABs should define their own system to comply with the legal requirements for independence and impartiality, but a system based on analysis of risk and control measures should be generally in place. This system will usually include a comprehensive risk analysis of the CAB's activities, its staff (including top-level management) and the activities of its organisation or related bodies. Risks posed to impartiality from each individual should be assessed with regard to past employment, consultancy services and financial interests. For instance, shares in companies certified by the notified body or in competitors of these companies (investment funds can be seen differently) as well as relatives of the person under analysis. Also, the risks linked to subcontractors/suppliers (1.2.1) of the manufacturer need to be assessed.

Section 2.4 of Annex VII also requires, as part of this system, a “multi-level” statement. Firstly, a general one, listing any existing or prior association with clients or devices or processes under assessment. This general one needs to be renewed from time to time (e.g. annually). In addition, there is a need for a written statement and verification by the notified body within each conformity assessment project.

Any involvement in processes (e.g. design, risk management, manufacturing processes) being related with the devices and quality management systems for economic operators covered by the application/designation needs to be seen as consultancy. Other activities not specifically linked with the product will be also regarded as consultancy (e.g. internal audits to manufacturers or client specific training).

I.10. Does a CAB that is part of a larger organisation need individual liability insurance?

The CAB is responsible for taking out liability insurance and therefore there must be evidence that the legal entity is covered by a liability insurance that fulfils the legal requirements. The contract with the insurance company can be signed by other legal entity of a larger organisation (i.e. mother company) provided that the contract gives the CAB the individual right to be protected against liability claims. The notified body must be able to invoke that right directly towards the insurance company, and not only indirectly via the company which has signed the contract (this is important e.g. in case of insolvency of the signing company or in case of unwillingness or inability of the signing company to effectively invoke the insurance contract towards the insurance company). Furthermore, the signing legal entity must involve the notified body in any change of insurance conditions affecting the medical devices conformity assessment activities of the CAB so that the notified body has the possibility to react if it considers that the coverage is insufficient.

Any change on the liability insurance which may affect the compliance of the notified body with the requirements set out in Annex VII should be communicated by the body to the authority responsible for notified bodies in accordance with articles 44 (1) of the MDR / 40(1) of the IVDR.

II. QUALITY MANAGEMENT SYSTEM

III. RESOURCES REQUIREMENTS

III.1. Is a complete re-authorization of existing personnel necessary to document satisfaction of the new qualification criteria under section 3 of Annex VII?

Yes, all personnel that will be used to perform conformity assessment tasks under the MDR/IVDR shall be authorized under the new criteria. For the satisfaction of the work experience criteria, the CAB can accept previous experience in a notified body but it cannot automatically grandfather authorisations (i.e. transfer authorisations) granted by other notified body or by the same notified body under the Directives. However, the experience in a notified body needs to be extensive and traceable and always specific to the tasks to be carried out and the specific technology or product (specific codes) in order to satisfy the MDR/IVDR qualification criteria. In addition, comprehensive and objective evidence of such previous experience in a notified body in the relevant scope shall be part of the personnel files.

III.2. What is the meaning of “permanent availability of sufficient personnel” within Section 3.1.1 of Annex VII?

In respect to the availability of personnel, MDR / IVDR Annex VII Section 3.1.1 do not establish the number of auditors / reviewers per code to ensure permanent availability of sufficient personnel. As a very minimum, it is considered that notified body should have one person available and authorised per applied-for scope code

and role as per Section 3.2 of Annex VII at the time of the joint assessment. Nevertheless, it is recommended that the notified body has two product reviewers/auditors authorised per code to ensure a sufficient capacity to allow fulfilment of other related requirements such as rotation of personnel. When this is not the case, an observation may be raised at the joint assessment in order to flag that for certain codes the available resources are limited.

The notified body is expected to have 2 auditors / reviewers available and authorised per applied-for scope in order to fulfil the legal requirements under Section 3.1.1 of Annex VII at the moment of its re-assessment joint assessment.

IV. PROCESS REQUIREMENTS

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The conformity assessment activities described under Article 52 / Article 48 apply to any certificate issued under the new regulations. As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore, all devices to be certified under the MDR / IVDR should be subject to an initial certification according to the applicable annex. The notified body should ensure that all requirements under the MDR / IVDR are fulfilled. It may not restrict its procedures to gap audits or gap file reviews.

It should be noted that MDD/AIMDD/IVDD certificates will remain valid until their expiration date and at the latest on 27 May 2024 as long as conditions laid down in Article 120(3) of the MDR and 110 (3) of the IVDR are complied with.

IV.2. What should be the criteria for auditing suppliers and subcontractors?

The MDR/IVDR established that the audit of the manufacturer premises must include an audit on the premises of subcontractors and/or suppliers if appropriate. Therefore, the notified body should have criteria for auditing these actors on the basis of their criticality. At the very least, the criteria defined in Section 4.5.2(b) of Annex VII should be applied (i.e. the control over the supplier/subcontractor and its influence on the conformity of the device is essential whereas the sole existence of a certificate against ISO 13485 is not sufficient).

IV.3. What is the meaning of "examinations and tests" to be included in a certificate in accordance with Section 10 of Annex XII of the MDR / IVDR? *(Position endorsed by the MDCG on 30 November 2018)*

Certificates do not need to include reference to relevant common specifications or harmonised standards as long as such information on all examinations and tests performed is traceable and available from e.g. report(s) which are mentioned in the certificate.

IV.4. What are the applicable requirements for voluntary certificate transfer under MDR Article 58 / IVDR Article 53? *(Position endorsed by the MDCG on 30 November 2018)*

While MDR Article 58(1) / IVDR Article 53(1) sets out the requirements for a transfer agreement, it does not specify the conformity assessment activities to be performed by the incoming NB.

he incoming NB may decide not to carry out full conformity assessment activities according to Article 52 MDR / Article 48 IVDR, as long as it does have sufficient information in respect to the conformity activities performed by the outgoing NB.

For quality management system certificates, the incoming NB needs to perform appropriate on-site audit(s) and assessments to ensure that the manufacturer in question applies the approved QMS and the post-market surveillance plan prior to the issue of any certificate. In respect to the assessment of technical documentations on a sampling basis, the oncoming NB shall review the previous assessment results together with a sample of a technical documentation and draw up or amend a sampling plan.

For product certificates (Annex IX Chapter II/Annex X), new certificates without a comprehensive (initial) review may be issued as long as the documentation received does not identify ongoing existing or other concerns.

The incoming NB assumes full responsibility for the new certificates issued following the transfer.

IV.5. What are the applicable requirements for OBL manufacturers?

The MDR / IVDR does not distinguish between OBL[3] and other manufacturers. There are just "manufacturers" and therefore OBL manufacturers must comply with the legal requirements, as any other manufacturer[4].

IV.6. What is the role of the internal or integrated clinician in the notified body´s assessment and decision-making process? *(Position endorsed by the MDCG on 9 April 2019)*

The internal or otherwise integrated clinician is responsible to identify when specialist input is required for the assessment of the clinical evaluation as defined in Section 3.2.4 of Annex VII of the MDR and IVDR. This decision will be made by the internal or integrated clinician on a case-by-case basis, based on the products covered by the applications lodged by the manufacturer and the clinical expertise available. The internal clinician or integrated clinician will be responsible for this process in all cases where the conformity of the device to the requirements of annex I is achieved also by

[3] OBL" (own brand label manufacturer) is a term used in the field that describes manufacturer that are supplied with the finished medical device by their supplier, who often is called "OEM" (original equipment manufacturer). Neither of both are defined in the MDR (or ever were defined in the Directives).

[4] Including but not limited to having: full and permanent access to the technical documentation; (ability for) post-market surveillance including post market clinical follow-up; sufficient technical competence; and control of the quality system (control of the design, manufacture and/or final verification and testing of the devices).

clinical data. In cases where demonstration of conformity to requirements of Annex I based on clinical data is not deemed appropriate (in accordance with Article 61(10)) the internal or integrated clinician will also examine the justification provided in order to assess its adequacy. The internal or otherwise integrated clinicians will decide if the review of clinical evaluation is to be carried out by themselves, to be delegated to other qualified staff or if it necessitates the input of external clinical experts. This process is also defined in Section 4.3 of Annex IX of the MDR and Section 5.4 of NBOG's best practice guide 2017-2 as endorsed by the MDCG.

Section 3.2.4 of Annex VII defines that there must be a clinician who is either internal (= employee) or otherwise integrated into the CAB's assessment and decision-making process. To be regarded as integrated, a clinician (who is not an employee) must have access to all the information, required to perform its activities, circulating in the CAB and must be involved in the internal processes in the same way as an employee, the only difference to an employee being that there is no employment contract, but a service contract and therefore this person should not be considered final reviewer or decision-maker as per 3.2.7 of Annex VII.

In addition to this, the internal or otherwise integrated clinician will clinically judge the opinion provided by any external expert (including verification of comparability and consistency of the assessments of clinical evaluations conducted by clinical experts) and will be responsible to make a recommendation to the decision maker on the adequacy of the clinical evaluation.

V. OTHER REQUIREMENTS

V.1. Are activities described under articles 16 and 17 of the Medical devices Regulation (MDR) and Article 16 of the in vitro medical devices Regulation (IVDR) will be covered during joint assessments?

Conformity assessment bodies (CABs) can issue certificates following the process described in articles 16 and 17 of the MDR and Article 16 of the IVDR but these are not considered conformity assessment activities covered by Chapter IV and Annex VII of the Regulations and therefore will not be part of joint assessments.

V.2. What is the meaning of "publicly available" as regards the list of standard fees of a notified body under Article 50 MDR / Article 46 IVDR? *(Position endorsed by the MDCG on 9 April 2019)*

Whenever the Regulations require certain information to be made "publicly available", that implies that a member of the public can access this information at any point in time, without the need for additional steps. In view of the public functions carried out by notified bodies, this requirement supports transparency of their activities.

Not only Article 111 MDR / Article 104 IVDR refer to different type of fees (i.e. fees levied by Member States), but also it uses different wording. It cannot therefore be used to support the interpretation of Article 50 MDR / Article 46 IVDR. Moreover, public availability of fees levied by Member States will usually result from the official publication of national laws setting out such fees (therefore, there will be no need to request information on such fees).