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Clarification on "*first certification for that type of device*" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746

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Introduction

For class D devices, Article 48(6) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR) establishes the conditions to be applied by the notified body to determine whether it has to consult the expert panel on the performance evaluation report of the manufacturer. These conditions are:

(1) the absence of common specifications for the class D device in question, AND
(2) where it is also the first certification for that type of device.

This guidance provides clarification on the meaning of these conditions and on the corresponding procedures to be followed by the notified body.

1. What is the meaning of "*the first certification for that type of device*" in accordance with Article 48(6) of Regulation (EU) 2017/746?

As mentioned in recital (53) of the IVDR, notified bodies should consult the expert panels where it is the first certification for that specific type of device and there is no similar device on the market having the same intended purpose and based on similar technology. Therefore, "*first certification for that type of device*" in Article 48(6) of the IVDR should be understood as the first certification under either Directive 98/79/EC or under Regulation (EU) 2017/746 by any notified body in relation to a product with a specific[1]:

- intended purpose, including all of the following:
    1. what is detected and/or measured,
    2. the function of the device such as screening, monitoring, diagnostic, *etc.*,
    3. the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate,
    4. whether it is automated or not,
    5. whether it is qualitative, semi-quantitative or quantitative,
    6. the type of specimen(s) required,
    7. where applicable, the testing population,
    8. intended user,
- analysis technology and process used, including:

[1] Taking into account Section 1.1 of Annex II to IVDR

1. the principle of the assay method or the principles of operation of the instrument.

If a device with a specific set of elements listed above:

- has been certified under Directive 98/79/EC, or
- is subject to an ongoing consultation of the expert panel under Article 48(6) of Regulation (EU) 2017/746, or
- has undergone a consultation of the expert panel under Article 48(6) of Regulation (EU) 2017/746, with the views published,

then notified bodies should consider any other device to be certified for the first time under Regulation (EU) 2017/746 with a similar set of elements as the same "type of device" irrespective of the manufacturer and therefore such devices will not need to be subject to a consultation with the expert panel.

Notes:

1) **Additional intended purpose outside Rule 1 or 2 of IVDR Annex VIII**: A class D device with an intended purpose X and another class D device with the intended purpose X and an additional intended purpose Y which falls outside of Rule 1 or 2 of IVDR Annex VIII should be considered of the same type for the purposes of the expert panel consultation, provided all other elements of the intended purpose and technology used are similar. For example, a device intended for screening blood donations for syphilis and another device intended both for screening blood donations for syphilis and to diagnose syphilis in the individual should be considered of the same type for the purposes of the expert panel consultation.

2) **Automated and semi-automated devices**: Automated and semi-automated devices should be considered of the same type for the purposes of expert panel consultation, provided all other elements of the intended purpose and the technology used are similar. For the purpose of this guidance, semi-automated tests could be considered as automated tests that still involve some manual operations such as transferring samples from one machine to another. Rapid tests, even if they include an automated reader, are not considered semi-automated.

3) **Technology**: The principle of the assay method or the principles of operation of the instrument refer to the overall assay or testing method(s), mechanism(s) or principle(s) of measurement, including the detection principle, which the device uses to achieve its intended purpose, e.g. sandwich enzyme-linked immunosorbent assay (ELISA), real-time polymerase chain reaction (PCR), time-of-flight mass spectrometry. For example, the following should be considered as different types of device for the purposes of the expert panel consultation:

a) a device using haemagglutination and another device using ELISA;
b) a device using a competitive immunoassay and another device using a sandwich immunoassay.

In contrast, devices using for example the following should be considered as the same type of device for the purposes of the expert panel consultation, provided all elements of the intended purpose are similar:

c) ELISA with colorimetric and chemiluminescent read-out;
d) Immunoassays with chemiluminescent read-out: (chemi)luminescence immunoassays (CLIA/LIA), electro-chemiluminescence detection immunoassays (ECLIA) and chemiluminescent microparticle immunoassays (CMIA).

4) **Multiplex and single analyte devices**: A multiplex device and the corresponding single device that both detect the same analyte should be considered of the same type for the purposes of expert panel consultation, provided all other elements of the intended purpose and the technology used are similar.

5) **Kits and class D components of those kits**: There could be cases where kits and the class D components of those kits are placed on the market separately, to be used with the same kit. In such cases the kit should be submitted to the expert panel as opposed to the class D components sold separately.

6) **Control materials**: If a device and control materials with assigned value (positive or negative if they fall in class D) are produced by the same manufacturer, they should be submitted to the expert panel together as part of one consultation procedure.

2. What procedure should a notified body follow to determine whether a given certification is the first for that type of device?

It is the notified body who has to decide whether the certification of the device in question is a first certification of its type. This means that the notified body should judge whether the above elements of the definition of “type of device” are similar to an already certified device or to a device with the consultation of the expert panel either ongoing or completed (see question 1) for it to be considered of the same type. For its decision, the notified body should:

- use its own knowledge and expertise;
- consider information provided by the manufacturer, including relevant research (e.g. scientific and market research);
- consider the information on type of device for the already completed and ongoing consultations of the expert panel, referred to in question 3.

If the notified body comes to the conclusion that it is the first certification of that type of device (either under Directive 98/79/EC or under Regulation (EU) 2017/746), and if no common specifications are available for that device, the notified body has to consult the expert panel.

The notified bodies should document their assessment of whether a given certification is the first of that type of device, and their corresponding conclusion.

3. How should the notified body indicate the type of device in its submission to the IVD expert panel?

When consulting the IVD expert panel, the notified body should provide, as part of the documents submitted to the Secretariat, the information requested in the template below describing the type of device.

The template duly completed by the notified body will be published on the website of the expert panel for the ongoing consultations of the expert panel. Once the expert panel has issued its views, the template will be part of the views.

Table 1: Template for description of the type of device for the purposes of expert panel views according to Art 48(6) of Regulation (EU) 2017/746

Intended purpose (P)		
P1	what is detected and/or measured *please specify the analyte(s) or marker(s), e.g. SARS-CoV-2 spike protein, Kel1 (K)*	
P2	function of the device *e.g. diagnosis, aid to diagnosis, monitoring, determining the infectious load, tissue typing etc*	
P3	the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate *e.g. hepatitis C infection, exposure to SARS-CoV-2, risk of HIV transmission in blood transfusion etc.*	
P4	whether it is automated or not	
P5	whether it is qualitative, semi-quantitative or quantitative	
P6	type of specimen(s) *e.g. whole blood, serum, saliva etc*	
P7	where applicable, the testing population *e.g. persons with specific health conditions, persons with specific symptoms, children in a certain age range*	
P8	intended user	
Technology (T)		
T1	principle of the assay method or principles of operation of the instrument *e.g. real-time PCR, qualitative PCR, digital PCR, sandwich immunoassay, competitive immunoassay, immunoturbidimetric assay etc.*	

4. **What is the meaning of the phrase "*where no CS are available*" in Art 48(6)?**

This should be understood as the case where no common specifications have been adopted and published in the Official Journal of the European Union for that type of device. After publication, the CS are considered "available", so the consultation of the expert panel is not required.

5. **If a notified body identifies that a consultation of an expert panel is currently ongoing for that type of device, what should it do regarding the certification process?**

This question does not concern the notified body that consults the expert panel on the first certification for that type of device, but rather the notified bodies that might be dealing with a second, third certification *etc*. while the consultation on the first certification is still ongoing. These notified bodies should not issue the certificate until the consultation of the expert panel on the first certification for that type of device is completed and the views are published. It is highly recommended that the notified bodies should give consideration to the views of the expert panel in its decision to issue the certificate.