MDCG 2019-3 Rev.1

Interpretation of Article 54(2)b

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MDCG 2019-3 Rev.1 changes	
Addendum on procedural aspects	New

Interpretation of Article 54(2)b

Article 54(2) of the MDR lays down three criteria that exempt devices from the pre-market clinical evaluation consultation procedure with the involvement of expert panels. In particular that article states that:

"The procedure referred to in paragraph 1 shall not be required for the devices referred to therein:

(a) in the case of renewal of a certificate issued under this Regulation;

(b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or

(c) where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device".

Interpretation of point (b) of Article 54(2) is unclear, notably in relation to the application of the word "marketed". In fact, while in point "a" the co-legislator explicitly indicates that the certificates referred to are those issued under the new Regulation, in point "b" there is no indication of whether a "device already marketed" refers to devices already marketed under the Directives or the Regulations.

This has raised questions from the public and from Member States.

As we are about to launch the procedures for the establishment of expert panels, clarification of this issue is extremely urgent, notably due to its impact on the future workload of panels and hence on relevant budget and workload estimations.

The following considerations seem to indicate that the expression "device already marketed" cannot be intended to refer to a device already marketed uniquely under the new Regulation:

- If the co-legislators had decided to restrict the application of point "b" to devices marketed uniquely under the MDR, they would have explicitly stated so, as they did for point "a";

- Article 54, together with other Articles (such as Article 61(6) and Article 120(3)), was written at the end of the negotiation process with a view to smoothen the

implementation of the new Regulation. Therefore the interpretation of the exemption should be understood in line with the spirit and intention of the co-legislators.

It has to be noted that, in respect to devices that have been marketed already under the relevant Directives, the word "modification" shall be meant as limited only to those modifications needed in order to comply with the new legal requirements introduced by the MDR[1] [2].

Addendum - Procedural aspects

Together with the application to be lodged under the applicable conformity assessment procedure, the manufacturer will provide the notified body with:

- a statement that it has marketed the device in question for the same intended purpose under the relevant Directive,
- copy of the last issued certificate(s) together with the certificate history, and
- a description of the modifications introduced to comply with the MDR

As part of its technical documentation assessment according to the MDR, the notified body will verify that the "modifications", as referred to in the main document, do not adversely affect the benefit-risk ratio. In particular, the notified body will verify:

- that the device in question had a valid certificate under the Directives,
- in case the certificate has been withdrawn, suspended[3] or expired, if there is an impact on compliance with the general safety and performance requirements, and
- that there is no pending assessment of changes for the device or outstanding non-compliance.

In addition, the notified body will verify the description of modifications provided and assess if these modifications are limited only to those needed in order to comply with the new legal requirements introduced by the MDR. Limitations of the intended purpose of the device should not trigger the consultation procedure in accordance to Art. 54.

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1 These devices will anyhow be subject to all applicable new MDR requirements, including those ones related to the clinical evaluation, and will need to be assessed by notified bodies against these new (and higher) requirements. This aspect together with the increased notified bodies' oversight foreseen under MDR should guarantee a high standard of safety for these products.

2 From a practical perspective, under the scenario where those products had to be subject to clinical evaluation consultation procedure with the involvement of expert panels, as a result of the application of criteria set in Annex IX 5c, in most if not all of the cases, the panel would decide not to give an opinion. Therefore, a very significant additional workload and financial burden would be created for an extremely limited added value.

3 Certificates for which the rationale for withdrawal or suspension is linked to lack of compliance with essential requirements may adversely affect the benefit-risk ratio of the device and will require a clinical evaluation consultation procedure.

In case that any of the abovementioned conditions are not fulfilled the notified body will follow the consultation procedure in accordance to Art. 54.

The assessment of the above conditions will be documented by the notified body in accordance with Section 4.6 of Annex VII in the clinical evaluation assessment report that will be made available to competent authorities in accordance with Art. 54 (1) and (3).

Clarifications in respect to the applicability of Art. 54(2)b with regard to devices already marketed under the MDR are to be provided in a separate guidance.