ANNEX

Publication of the notice under Article 34 of Regulation (EU) 2017/745 after 26 May 2020: preliminary overview of legal consequences

Article 123.3 of the MDR: EUDAMED-related obligations that will not apply on 26 May 2020

Article 123.3 letter (d) MDR provides a specific possibility that EUDAMED is not fully functional by the date of 26 May 2020, i.e. the date for general entry into application of the regulation under Article 123.2.

In particular, Article 123.3 letter (d) MDR clarifies that if EUDAMED is not fully functional on 26 May 2020, the MDR obligations and requirements that relate to EUDAMED will apply later from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3).

Article 123.3 letter (d) MDR provides a list of the concerned MDR provisions that contain obligations and requirements related to EUDAMED and clarifies that, until the date corresponding to six months after the publication of the Article 34(3) notice, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting such obligations and requirements related to EUDAMED[1].

Article 123.3 letter (e) MDR contains further provisions for the case where EUDAMED is fully functional later than 26 May 2020.

In particular, Article 123.3 letter (e) provides that:

> "*Article 29(4) and Article 56(5) shall apply from 18 months after the later of the dates referred to in point (d)*", where reference is made to Article 123.3 letter (d).

In the current circumstances, the "*later of the dates referred to in point (d)*" mentioned in Article 123.3 letter (e) will be the date corresponding to six months after the date of publication of the notice referred to in Article 34(3).

Article 29(4) MDR on registration in EUDAMED of information relating to the device, and Article 56(5) MDR on registration in EUDAMED of information relating to certificates will, therefore, apply from 18 months from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3), i.e. 24 months after the date of publication of the notice referred to in Article 34(3).

Article 122 of the MDR: provisions of the Directives 90/385/EEC and 93/42/EEC that will remain applicable

Based on Article 123 MDR, the Commission and the competent authorities of the EU Member States are called to identify the provisions of Directives 90/385/EEC and 93/42/EEC that correspond to the EUDAMED-related MDR obligations and requirements that will not enter into application on 26 May 2020.

[1] The last paragraph of Article 123.3 letter (d) MDR provides that: "*Until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications*".

In this respect, Article 122 provides first guidance, as it clarifies that the repeal of some provisions of the Directives 90/385/EEC and 93/42/EEC will depend on when the notice referred to in Article 34(3) is published.

The first paragraph of Article 122 MDR provides that the provisions of the Directives 90/385/EEC and 93/42/EEC are repealed with effect from 26 May 2020, with the exception of the specific articles mentioned in its four indents, whose repeal will depend on the date of publication of the notice referred to in Article 34(3).

In particular, the first paragraph of Article 122 provides that:

> "*Without prejudice to Articles 120(3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2020, with the exception of:*
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> — *Articles 8 and 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation;*
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> — *Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation;*
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> — *Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation; and*
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> — *Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation".*

The "*later of the dates referred to in point (d) of Article 123(3) of this Regulation*" mentioned in the fours indents referred above shall be intended as the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). This implies that:

- The provisions mentioned in the first and third indents will be repealed from the date corresponding to six months after the publication of the notice referred to in Article 34(3);
- The provisions mentioned in the second and fourth indents will be repealed from the date corresponding to 24 months after the publication of the notice referred to in Article 34(3).

Article 122, therefore, represents the starting point in identifying the relevant articles in the two Directives that will remain applicable even after 26 may 2020. This Article is the basis to develop a more detailed analysis of the relevant provisions of the Directives, notably in the context of CAMD Transition Sub Group, in order to assess how correspondence with the provisions listed in the first paragraph of Article 123.3 letter (d) MDR can be ensured.