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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

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1. INTRODUCTION

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices[1] and Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices[2] were adopted on 5 April 2017 and entered into force on 25 May 2017. Regulation (EU) 2017/745 applies since 26 May 2021[3]. Regulation (EU) 2017/746 will apply from 26 May 2022[4].

Medical devices and *in vitro* diagnostic medical devices have a fundamental role in saving lives by providing healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. Regulations (EU) 2017/745 and (EU) 2017/746 aim to provide a robust, transparent and sustainable regulatory framework in order to ensure a high level of safety and performance of medical devices and *in vitro* diagnostic medical devices, while supporting innovation.

Regulations (EU) 2017/745 and (EU) 2017/746 empower the Commission to adopt several delegated acts. The Commission is required to report to the European Parliament and the Council on the delegations of power not later than nine months before the end of the five-year period.

2. LEGAL BASIS

With this report, the Commission meets the reporting requirements established in Article 115(2) of Regulation (EU) 2017/745 and Article 108(2) of Regulation (EU) 2017/746. Pursuant to those provisions, the power to adopt delegated acts referred to in the provisions listed therein (i.e. Articles 1(5), 3, 10(4),18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) of Regulation (EU) 2017/745 and Articles 10(4), 17(4), 24(10), 51(6) and

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1 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1.

2 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176.

3 Its date of application had been postponed by one year due to the COVID-19 pandemic by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, OJ L 130, 24.4.2020, p. 18.

4 Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices, OJ L 19, 28.1.2022, p. 3, has introduced additional transitional provisions in the Regulation (EU) 2017/746.

66(8) of Regulation (EU) 2017/746[5]), is conferred on the Commission for a period of five years from 25 May 2017.

Article 115(2) of Regulation (EU) 2017/745 and Article 108(2) of Regulation (EU) 2017/746 lay down that the delegations of power are to be tacitly extended for periods of identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. EXERCISE OF THE DELEGATIONS

The Commission has not yet exercised the delegated powers conferred to it under the respective provisions of Regulations (EU) 2017/745 and (EU) 2017/746. This is primarily due to the fact that Regulation (EU) 2017/745 has been applicable since 26 May 2021 and Regulation (EU) 2017/746 will apply from 26 May 2022. Hence, there is at present only limited experience on their application in practice. Further explanations are provided below for each of the empowerments.

- Products without an intended medical purpose

  Article 1(5) of Regulation (EU) 2017/745 empowers the Commission to adopt delegated acts to amend Annex XVI to that Regulation. Annex XVI lists groups of products without an intended medical purpose as referred to in Article 1(2). The Commission is empowered to add new groups of products in order to protect the health and safety of users, other persons or other aspects of public health. The groups of products listed in Annex XVI are still up to date.

- Amendment of the definition of 'nanomaterial' and related definitions

  Article 3 of Regulation (EU) 2017/745 empowers the Commission to adopt delegated acts to amend the definition of 'nanomaterial' set out in Article 2(18) and the related definitions of 'particle', 'agglomerate' and 'aggregate' set out in Article 2(19), (20), (21) in light of technical and scientific progress and taking into account definitions agreed at Union and international level. The before-mentioned definitions are based on Commission Recommendation 2011/696/EU[6] which has not yet been updated. A review of that Recommendation is ongoing and is expected to result in the adoption of a revised Recommendation and accompanying staff working document in the first half of 2022. Should the definition of 'nanomaterial' be amended in that Recommendation, the Commission will assess the need to amend the corresponding and related definitions in Regulation (EU) 2017/745, in order to maintain consistency with that Recommendation.

- Elements to be included in the technical documentation and technical documentation on post-market surveillance

[5] In addition, Article 40(11) of Regulation (EU) 2017/746, which is not mentioned in Article 108 of that Regulation, contains an empowerment to adopt delegated acts.

[6] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, OJ L 275, 20.10.2011, p. 38.

Article 10(4) of Regulations (EU) 2017/745 and (EU) 2017/746 empowers the Commission to adopt delegated acts to amend, in the light of technical progress, the elements to be included in the technical documentation and technical documentation on post-market surveillance pursuant to Annexes II and III to Regulations (EU) 2017/745 and (EU) 2017/746. Technical progress has not yet given rise to the need for any amendments.

- Exemption from the requirement of an implant card

Article 18(3) of Regulation (EU) 2017/745 includes a list of implants exempted from the requirements of an implant card and empowers the Commission to adopt delegated acts to amend that list by adding other types of implants to it or by removing implants therefrom. To date, no need for updating the list has arisen in view of well-established technologies or in order to protect the health and safety of patients, users or other persons or other aspects of public health.

- Minimum content of the EU declaration of conformity

Article 19(4) of Regulation (EU) 2017/745 and Article 17(4) of Regulation (EU) 2017/746 empower the Commission to adopt delegated acts to amend, in the light of technical progress, the minimum content of the EU declaration of conformity set out in Annex IV to Regulations (EU) 2017/745 and (EU) 2017/746. Technical progress has not yet given rise to the need for an amendment.

- Information to be submitted as part of the Unique Device Identification (UDI) system

Article 27(10) of Regulation (EU) 2017/745 and Article 24(10) of Regulation (EU) 2017/746 empower the Commission to adopt delegated acts to amend Annex VI to the respective Regulation in the light of technical progress or international developments in the field of Unique Device Identification. The Commission is currently preparing a delegated act pursuant to Article 27(10), point (b), of Regulation (EU) 2017/745, amending Annex VI to Regulation (EU) 2017/745 as regards UDI assignment for contact lenses.

- Frequency of complete re-assessment of notified bodies

Article 44(11) of Regulation (EU) 2017/745 and Article 40(11) of Regulation (EU) 2017/746 empower the Commission to adopt delegated acts to modify the frequency at which the complete re-assessment of notified bodies with regard to the fulfilment of the requirements in Annex VII to the respective Regulation is to be carried out. Currently, Article 44(10) of Regulation (EU) 2017/745 and Article 40(10) of Regulation (EU) 2017/746 provide for such re-assessment three years after notification and again every fourth year thereafter. The first notified body under Regulation (EU) 2017/745 was designated in January 2019[7], so there is little practical

[7] Currently, 27 notified bodies are designated under Regulation (EU) 2017/745 (EUROPA - European Commission - Growth - Regulatory policy - NANDO) and 6 notified bodies are designated under Regulation (EU) 2017/746 (EUROPA - European Commission - Growth - Regulatory policy - NANDO).

experience which would have justified the adaptation of the frequency of re-assessment laid down in the Regulations.

- Exemption of certain well-established technologies from assessment of technical documentation for every single device

  Article 52(5) of Regulation (EU) 2017/745 empowers the Commission to adopt delegated acts to amend the list of devices in Article 52(4), second subparagraph, of Regulation (EU) 2017/745 by adding other types of class IIb implantable devices to that list or removing devices therefrom. The list contains class IIb implantable devices exempted from the assessment of the technical documentation as specified in Section 4 of Annex IX to Regulation (EU) 2017/745 for every single device. The assessment of at least one representative device per generic device group suffices. It may be justified in the future in view of well-established technologies to add further devices to that list or to remove devices from the list in order to protect the health and safety of patients, users or other persons or other aspects of public health.

- Minimum content of certificates issued by a notified body

  Article 56(6) of Regulation (EU) 2017/745 and Article 51(6) of Regulation (EU) 2017/746 empower the Commission to adopt delegated acts to amend, in the light of technical progress, the minimum content of certificates issued by a notified body. The minimum content of certificates issued by a notified body is listed in Annexes XII toRegulations (EU) 2017/745 and (EU) 2017/746. Both Regulations include transitional provisions allowing devices to be placed on the market with certificates issued in accordance with the previous Directives. Therefore, there is not enough practical experience on the issuing of certificates under the Regulations which would have given rise to amend their minimum content.

- Exemption of certain well-established technologies from assessment of technical documentation for every single device and from the requirement to perform clinical investigations

  Article 61(8) of Regulation (EU) 2017/745 empowers the Commission to adopt delegated acts to amend both the list in Article 52(4), second subparagraph, already mentioned above, and the list in Article 61(6) point (b) of Regulation (EU) 2017/745 containing implantable devices exempted from the requirement to perform clinical investigations pursuant to Article 61(4) of Regulation (EU) 2017/745. It may be justified in the future in view of well-established technologies to add further devices to those lists or to remove devices from the lists in order to protect the health and safety of patients, users or other persons or other aspects of public health.

- Documentation regarding the application for clinical investigation and interventional clinical performance studies

  Article 70(8) of Regulation (EU) 2017/745 and Article 66(8) of Regulation (EU) 2017/746 empower the Commission to adopt delegated acts to amend, in the light of technical progress and global regulatory developments, Annex XV, Chapter II, to

Regulation (EU) 2017/745 and Annex XIV, Chapter I, to Regulation (EU) 2017/746, which lay down the requirements for documentation regarding the application for clinical investigation and for interventional clinical performance studies and other performance studies involving risks for the subjects of the studies, respectively. To date, no need for updating the documentation requirements has arisen.

- Tasks of expert panels and expert laboratories

Article 106(15) of Regulation (EU) 2017/745 empowers the Commission to adopt delegated acts to amend the tasks of expert panels and expert laboratories, which are listed in Article 106(10) of Regulation (EU) 2017/745. Expert panels were designated by Commission Implementing Decision (EU) 2019/1396[8] and started their work in April 2021. Expert laboratories have not yet been designated. To date, no need for changing the tasks of expert panels or expert laboratories has arisen.

4. CONCLUSION

The Commission sees the need for a tacit extension of the delegations of power provided for in Article 115(2) of Regulation (EU) 2017/745 and Article 108(2) of Regulation (EU) 2017/746 for a period of five years, in accordance with those Articles.

The need to develop and adopt rules based on the empowerments granted by Article 115(2) of Regulation (EU) 2017/745 and Article 108(2) of Regulation (EU) 2017/746 may arise in the future. The rationale for the delegations of power has not changed. It is important to maintain the necessary flexibility in the legal framework, to supplement or adjust it to technical and scientific developments with a view to protect health and safety of patients, users and public health in general based also on more experience gained with the application of the Regulations.

The Commission invites the European Parliament and the Council to take note of this report.

[8] Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices, OJ L 234, 11.9.2019, p. 23.