Statement

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Joint Statement of

Berufsverband Deutscher Pathologinnen und Pathologen e. V. (BDP)
Deutsche Gesellschaft für Pathologie e. V. (DGP)
Berufsverband Deutscher Humangenetiker e. V. (BVDH)
Deutsche Gesellschaft für Humangenetik e. V. (GFH)
Berufsverband Deutscher Laborärzte e. V. (BDL)
Akkreditierte Labore in der Medizin e. V. (ALM)
Berufsverband der Ärzte für Mikrobiologie, Virologie und Infektionsepidemiologie e. V. (BÄMI)
Spitzenverband Fachärztinnen und Fachärzte Deutschlands e. V. (SpiFa)

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR): Call for action to ensure availability of in-house in vitro diagnostic medical devices and to promote innovation in personalized medicine

To continue providing in-house in vitro diagnostic medical devices and also offer the best possible care for small patient groups, a significant reduction in bureaucracy and adaptation of regulatory requirements for devices manufactured and used only within health institutions, so-called in-house devices (IH devices) are necessary. The current preference for commercial CE devices in accordance with Article 5(5)(d) IVDR jeopardizes innovation and rapid access to new diagnostic and therapeutic procedures. The following actions are necessary:

1. **Exemption from the equivalence clause:**
   Limitations on IH devices, where equivalent commercial CE devices are available, must be dropped to ensure long-term sustainability and medical innovation in diagnostics and therapy and to enable prompt adaptation to patients‘ needs. If an IH device and a CE device are equivalent, the regulation‘s protective purpose ceases to exist. A general preference for the CE device over the IH device is unjustified discrimination, an active interference in the decision-making competence of medical diagnostic institutions and lacks any regulatory basis or otherwise substantiated justification. Therefore, we call for removing Article 5(5)(d) IVDR without replacement.

2. **Simplified regulatory requirements:**
   Medical diagnostic facilities must benefit from reduced requirements in Annex I and streamlined documentation duties. In Germany, established quality management and risk management systems in accordance with the Guidelines of the German Medical Association on Quality Assurance in Medical Laboratory Examinations (Rili-BAEK), DIN EN ISO 15189, and DIN EN ISO 17020 have ensured high patient safety for years. With DIN EN ISO 15189, which has been revised in 2023 and is also adhered to in DIN EN ISO 17020, a modern regulatory system is available.

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Statement Continuation

3. **Adaptation of the requirements for in-house devices for small patient groups:**
   The care for small patient groups requires special arrangements. Various special regulations such as Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products or the FDA's Humanitarian Device Exemption already allow for this particular necessity. Accordingly, the requirements of Article 5(5) IVDR for IH devices for small patient groups, for rare diseases, and in cases of low availability of sample material must also be adapted to ensure diagnostic service for these patient groups. If only a small number of cases or limited sample material is available, proof of clinical performance (Annex I Chapter II No. 9.1 b IVDR) of IH devices used in diagnosis must be omitted or provided successively. This would allow proof of performance for in-house devices while ensuring high-quality care for individual patients.

These requirements are essential to promoting innovation, enabling evidence-based diagnostics in rare diseases and personalized medicine, and ensuring long-term patient care.

Referenzen

1. 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 (IVDR)
   https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32017R0746
2. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products
   https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32000R0141
3. humanitarian device exemption of the FDA, updated 13.01.2025
   https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption

Further information

https://www.bvdh.de/newsdownload/250/Gemeinsame_Stellungnahme_IVDR_07-2024.pdf

On behalf of the Board of the Professional Association of German Pathologists (Berufsverband Deutscher Pathologinnen und Pathologen e. V.) and the listed professional associations and societies.

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