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Sent: Wednesday, 17 September 2025 21:58
To: [redacted]
Cc:
Subject: Rückmeldung zu Herausforderungen der MedTech Industrie bzgl. des AI Acts

Sehr geehrt[redacted]

vielen Dank für den Austausch mi[redacted]uf der CIO-Runde vergangene Woche. Wie besprochen, geben wir Ihnen anbei ein paar Beispiele, die aufzeigen, in welchen Bereichen der AI Act nicht praktikabel ist und mit denen wir als Hersteller von Medizintechnologie und digitalen bzw. KI-Lösungen Schwierigkeiten haben. Der Einfachheit halber schicken wir Ihnen diese Anmerkungen in Englisch.

Wir sind dazu auch mit Ihren Kolleginnen und Kollegen vom BMG in Kontakt, wertschätzen es aber außerordentlich, wenn Sie unsere Punkte in die Diskussion mit der Kommission einbringen.

Insgesamt begrüßen wir die Ziele des AI Acts und die Intention, dass Lösungen basierend auf künstlicher Intelligenz nur sicher entwickelt und benutzt werden kann und unterstützen das in unseren eigenen Entwicklungstätigkeiten. Jedoch wünschen wir uns insbesondere einen sektoralen Ansatz für die Medizintechnologie, in dem die bereits bestehenden strengen Regelungen zu KI aus der Medical Devices Regulation bzw. der In Vitro Diagnostics Regulation in den AI Act integriert werden und Doppelregulierung vermieden wird.

Melden Sie sich gerne bei uns, wenn Sie zu einzelnen Punkten Fragen haben.

Mit freundlichen Grüßen

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Examples of contradictions/ambiguities with existing regulations (MDR and EU AI Act)

The published FAQ document on **Interplay between MDR/IVDR and AI Act** (MDCG 2025-6/AIB 2025-1) by the EU Commission **does not give helpful insights** as they are mainly rephrasing the law à Clear.
Particularly, the EU AI Act is not specific enough to MDs/IVDs:

- No information on how AI Act and EU MDR relate to each other
- No definition on what is the AI System and what is the Component
- No definition on whether the Medical Device actually is the AI System
- Definition of high-risk AI Systems is difficult to interpret, also no good guidance is available; “Safety Component” results in highly controversial discussions

- **General: Critical timeline, missing (harmonized) standards**, **no NCAs, no accredited NBs**

Regarding Notified Bodies:

- definition of product-specific codes (codes aim to reflect the diversity of high-risk AI systems (e.g., medical software, biometrics, etc.)) are still underway
- unclear how many NB will be able to assess AI-enabled medical devices or when they will be operational
- depend on the formal appointment of notifying authorities - a step some Member States **(incl. Germany) have yet to complete (the deadline already missed**).
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Regarding standards: Even if there were standards for the AI Act available**, they are not "usable" for Medical Devices**

- standards are generic, non-industry specific
- adaption for Medical Devices is needed

Transparency EU AI Act Art. 50: seems not to be written for medical devices, we spend a lot of time with the interpretation, however the timeline is critical as applicable in 11 months **(2.8.2026) – for all products incl. Medical Devices**, even if the **Date of Application for Medical Devices is 1 year later 2.8.2027**).

- Art. 50(1) and recital 133: risk of impersonification and deception
  > does not fit to MDs
  > even if guidance is provided soon by EU Commission, it would **require additional work for manufacturers and would need re-adaption of processes** that are currently implemented **(guidance too late and not specific for MDs)**

Fundamental rights: harm to persons (e.g. radiation) vs. medical care/necessity.

- The **Fundamental Right Charta are generally applicable** and to **introduce those obligations (ensuring the fundamental rights) to economic operators acc. EU AI Act makes it only more complicated and not helpful.**

GDPR

Including the GDPR on the EU DoC (Declaration of Conformity) of the AI Act does not make sense as the GDPR does not require a CE mark and a Conformity Assessment Procedure incl. a NB

- **EU AI Act and GDPR-related challenges: Difficult "EU-level balancing":**
- Parallel scope of application of MDR/IVDR, EU AI-Act and GDPR, although **different supervisory authorities act** partly on a sectoral basis and partly with a focus on data protection.
  > **Consistent supervisory practice is required: Different assessments of identical setups by supervisory authorities** lead to **uncertainty and delays**.
  Example: AI training needs relevant and sufficiently representative data (Art. 10, 26 (3) AI Act) versus AI training with adequate, relevant and limited data (Art. 5 (1) lit c GDPR, "Data Minimization Principle").
- The majority of **"inventory data" is not collected for AI training purposes**.
  Risk: not compatible with the respective AI training purpose, the use of such data for AI training is not legitimate unless there is another legal basis for its use.

Examples of unclear wording that is already clearly defined in the MDR

- Art. 111 of EU AI Act does not grant any transitional provisions or "grandfathering" of such AI systems (**nothing comparable toArt. 120 EU MDR**).

- This will lead to **less products being available on the EU market** – hard to fulfill the training- and design-related requirements(e.g. having all training, validation und testing data)
- In our view the principle should apply only to those high-risk AI systems which were developed and trained following **entry into force of the AI Act.**
- **All AI-enabled MDs** (with "locked" AI – means not continuously learning) **are covered by the EU MDR/IVDR** even if AI is already included. **The protection goals that are addressed by the EU AI Act are already addressed by the EU MDR/IVDR (incl. safety and security)**.
- **The definition of "safety component"** in Art. 3 (14) AI Act **significantly deviates from the definition** in Art. 3 (3) of **the Machinery Regulation**.
- It is not clear, **how the rules applicable for clinical investigations** pursuant to the medical device regulation (Art. 61 et seq. MDR) **relate to the rules for testing of high-risk AI systems** in real world conditions (Art. 60 et seq. AI Act).
- **Current language of the AI Act does not seem – other than under the MDR – to allow distributors to apply a sampling method for the required verifications** (compare Art. 24 (1) AI Act with Art. 14 (2) 2nd sentence MDR)
- It is not clear, whether Art. 16 lit. (l) AI Act is meant to "remind" of the applicability of the respective accessibility directives (within their limits of application) or whether it is intended to stipulate an accessibility requirement on its own (and beyond those Directives, see Recital 80 of the AI Act: "full compliance with accessibility requirements, including Directive …").
- While Art. 6 (1) and the corresponding obligations **relevant for medical devices will apply from 2 August 2027**, the **transparency obligations** pursuant to Art. 50 would seem to apply for medical devices **already from 2 August 2026, thus drastically shortening the time for needed design changes**.
- The information to be provided by **GPAI model providers pursuant to the AI Act** would **not be sufficient for the conformity assessment**.
- Art. 25 (2) last sentence is too narrow since it **allows the "initial provider" only to forbid that its AI system is changed into a high-risk AI system** (thus only the scenario described in Art. 25 (1) (c)), but not the scenarios under Art. 25 (1) (a) and (b) which are much more relevant for medical devices, thus **imposing an unacceptable obligation on the "initial provider" of an AI-powered medical device to make available to information and know-how to third parties who have modified the device without appropriate authorization.**