ResMed

ResMed consultation response

Artificial Intelligence Act

General legal framework:

- ResMed welcomes the proposal for horizontal legislation overseeing AI, the proposed efforts to ensure the safety and trustworthiness of AI, and the creation of an ecosystem to support innovation and uptake of AI within the EU and beyond. To support this ambition, ResMed urges that the rules surrounding AI are clear and workable, and the appropriate guidelines are provided by regulators to implement the proposed requirements across the AI value chain, in particular as regards interaction with existing sectoral legislation.
- ResMed welcomes the Commission defining AI in coordination with the OECD, prohibiting certain practices and taking a risk-based approach to regulating AI systems.
- ResMed calls upon the Commission to ensure the legislative framework is developed with future innovations in mind, to ensure that new developments are supported and encouraged rather than overregulated.

Ensuring harmonisation with the wider regulatory framework:

- ResMed welcomes the effort for harmonisation with other existing legislation but urges that the legislation reduces overlap and simplifies compliance with other related legislation to the greatest extent possible, of particular note are the Medical Devices Regulation (MDR), the In Vitro Diagnostics Regulation (IVDR), the General Data Protection Regulation (GDPR), the Data Governance Act (DGA) and the European Health Data Space (EHDS).
- ResMed welcomes the streamlining of additional requirements through the existing conformity assessment process involving notified bodies and urges that the proposed legislation does not create duplication or overregulation. Whilst, looking forward to more clarity on how the AIA and MDR/IVDR conformity assessments will function in practice, how overlap of technical documentation can be reduced and how the competent authorities will be supported in overseeing and evaluating AI systems.
- In order to minimise any challenges which will arise due to the ex-ante conformity assessment, ResMed calls for the Commission to clarify the interplay between legislation which overlaps with the AI regulation and encourage an approach that relies on self-regulation and industry standardisation.
- ResMed looks forward to further clarity on how healthcare AI products or the safety components of products which fall outside of the scope of Rule 11 of the MDR will be regulated, in particular those involved in research.
- ResMed looks forward to further clarity on post-market surveillance obligations, the types of data and experiences to be collected, and how such data will need to be stored and protected, such that the proposed legislation does not create duplication or overregulation with MDR/IVDR post-market requirements.

Trust:

- ResMed urges that the legislation builds trust in AI, including among public health practitioners and patients, by ensuring appropriate protections are in place, such as maintaining data for monitoring performance, and limiting the claims that can be made about AI systems. Additionally, education, training and up/re-skilling will be important to ensure that healthcare professionals and patients are comfortable using AI technologies.

Access to data:

- ResMed calls attention to the importance of the secondary use of healthcare data for innovation and urges the legislative framework to allow for the reuse of health data for AI development purposes as well as for research insights.
- In order to support the EU in realizing its vision for AI in Europe, ResMed urges the Commission to clarify the roles of controller, processor and joint controller under the GDPR to enable a competitive and innovation friendly environment for healthcare AI.

AI value chain:

- Whilst additional safety provided by looking at the entire AI value chain is welcomed, ResMed urges for this not to add extensive additional requirements which would stymie innovation and the free flow of data -- hindering trade, including digital trade, which is key to bringing AI systems to the EU market and, equally, allowing EU companies to fully participate in global efforts to innovate.

Foreseen European AI Board:

- ResMed welcomes the proposed European AI Board but calls for the Commission to look to lessons learned from the GDPR enforcement model and looks forward to more clarity on how national authorities will be supported in the necessary up/re-skilling. Additionally, the European AI Board should ensure it works collaboratively with and does not duplicate or undermine the work of the European Data Protection Board or the European Data Innovation Board foreseen under the DGA.
- ResMed commends the proposal for an independent expert group to assist the European AI Board in its work. Encourages the Commission to ensure that the group take into account and adequately represent the specificities of the healthcare sector including public authorities, clinical research, health practitioners and patients, and private companies via consultative processes.