

AI White Paper Consultation

ADDITIONAL COMMENTS FROM EUCOPE TO THE ONLINE CONSULTATION:

On product safety legislation:

As the Commission considers potential updates to product safety legislation and incorporating new safety concepts that are robust to the changing nature of AI algorithm-based products, the industries investing in adoption of these new technologies will benefit from step-wise, sector-specific guidance to minimize risk and ensure that consumers benefit from proper implementation of these advancements.

In highly regulated industries, such as pharmaceuticals, companies are subject to strict audit and inspection requirements. An agreed GxP framework is required to ensure that AI-based decision-making is sufficiently practical and auditable when used in the context of decision-making of benefit-risk evaluation. For example, for an AI-based tool that enables an internal decision point on safety, how much data should be retained to document a decision at a point in time? For example, if a company used AI to determine seriousness of a post-marketing safety case and an inspector enquired as to the decision process for that case, it may be difficult, if not impossible, to fully document the step-wise process, as AI continually adjusts to new data.

Guidance on the level and type of risk mitigations and minimum standards for process controls would not only result in a benefit to patient safety but also speed the uptake of AI in product development. Moreover, given the nature of AI, as new regulations are created re-training will be required. General guidance and an appropriate window for regulations to take effect will make compliance more feasible to maintain.