SANOFI comments to the European Commission's White Paper on Artificial Intelligence

June 2020

Sanofi welcomes the opportunity to provide comments to this white paper in helping further shape the application of AI in Europe, notably within the healthcare industry. Artificial intelligence is already embedded in many of Sanofi's activities, from facilitating internal processes to the research and development of diseases and in enhancing product development for the benefit of patients worldwide. Sanofi has also been at the forefront in enabling the use of AI in our manufacturing sites to improve access and ensure the availability of our products. This has been catalysed with our digital manufacturing facility in Framingham that was launched last October 2019 and is being expanded in many of our manufacturing activities.

Sanofi supports the objectives of the EC to promote the adoption of appropriate and hence trustworthy AI and the ambition to establish leadership where it has excellent capabilities. From these seeds, a prospering AI ecosystem can crystallise.

Key points that we recommend highlighting in the proposed regulatory approach:

- A risk-based approach to AI is welcomed. A new EU regulation should only be pursued where procedural and control alignment and common standards are needed, i.e. for high risk applications in EU markets. A Regulation on high risk AI applications may well be the fastest way to establish a common ecosystem for AI to foster. However, care should be taken when intending to harmonize across sectors.
- AI regulation must be pragmatic and proportionate to the risk involved.
- We welcome the parallel EU data strategy to help establish this essential aspect to successful AI.
- Any proposed AI regulation or standards must apply to all individuals/parties covering EU-related individuals/parties, irrespective of the location of the AI user/developer.

Key points to consider including in the proposed regulatory approach:

- Establish a regulatory sandbox to use as a safe test environment for AI applications notably in lower risk areas, and with sufficient government/regulatory oversight. Through a sandbox, companies will have the opportunity to understand the regulatory requirements set and allow governments to gain further understanding of the risks, challenges, and solutions to these technologies. Furthermore, clarifying the interpretation & practical applicability of GDPR in this context would be helpful.

- In the conformity assessment process, the acceptance criteria for risks associated with new AI applications should take into consideration the relative risk of the proposed new AI solution and existing good practices as opposed to the residual absolute risk or hypothetical risks still inherent with the that solution. For example, if a new medical device correctly identifies a specific pathology in 95% of the patient scans, then this may be a remarkable relative improvement over current diagnostic practice which may be only 90% accurate, despite 5% incorrect cases. This approach to safety can be applied across industries and acceptability should be based on both the marginal benefit and risk associated with the new solution.

- We recognise the importance of transparency requirements on AI, such as in explaining its intended use, the analysed information, and output in lay language or in a suitable format. In this case, we recommend the importance of achieving balance between safeguarding proprietary knowledge of the producer from disclosure and protecting their intellectual property rights. As various approaches and tools are currently being explored and developed to support the "explicability" of AI decisions, other approaches could also be considered, such as:
    - First, it is also essential to mandate regular review of AI performance, robustness/validation and potential bias post launch, in particular but not limited to adaptive AI solutions.
    - Second, audit trails and moderate documentation requirements could help to at least be able to inspect output creation ex-post.

  Regulation around the approaches or tools that support the "explicability" of AI should anticipate that such approaches/tools will improve over time and that that any regulation on this will also be used to help consumers make more informed choices on the reliance they put on these approaches/tools. As soon as the appropriate approaches/tools are identified, the respective documentation and control procedures related to the "explicability" of an AI system can be waived.

- We favour a regulatory approach where the developer has obligation to comply by defined EU standards, certifies compliance and must be able to demonstrate compliance over an ex-ante approval by authorities. This allows for a more dynamic approach, while avoiding any bureaucratic overhead and delay. We also support a voluntary label, irrespective of it being a high or low risk AI application. Consumer protection can be assured by maintaining their accountability on their data and ensuring an effective liability system. This includes establishing or appointing authorities that conducts inspections through random sampling. We think there is an opportunity to learn from the Medical Device Regulation, where the overhead on manufacturers and Notified Bodies has been excessive. A lighter approach is important, especially for small innovative companies. Any new regulation on AI should specifically also remove obstacles identified in some countries which unreasonably hinder the uptake of AI.

- We think the EU liability framework should not be fundamentally changed, but we agree that standalone software could be included or further developed as part of the product liability framework. For example, when AI is sourced from a supplier and is part and parcel of a product or service offered to consumers, the producer of the product or service should assume accountability of the product as a whole. The burden of proof for tort cases should still be on the claimant in principle. This being said, we acknowledge the difficulty for consumers to provide evidence on malfunctions. This should be addressed by an obligation of the producer to transparently inform the consumer. Any evidence requirements of the producer should be limited to product claims made, processes, and due diligence applied as outlined in the standards set forth in the regulations or, if applicable, using the label under which the AI was produced.
    - Additional standards which could be included in regulations and labels may include transparency requirements about the performance of a device and the circumstances under which they operate, as well as the risks if these

conditions cannot be upheld (e.g. loss of connectivity or cyber risk). Waiving these risks as a producer should only be allowed to the extent that they cannot reasonably be expected to control them. AI systems should not be made a legal subject in their own right.

- An error reporting process for AI could be envisaged, similar to when reporting adverse event on drugs or anonymous error reporting systems in clinical practice. This could help disclose AI malfunctions to learn as a community and improve (examples exist with pilots or physicians)
- Given the rapidly evolving landscape around AI, interim and ex-post reviews of introduced regulation and initiatives around this would be greatly welcomed, and we would be happy to continue working with the European Commission and the relevant regulators and member states in providing valuable insights and expertise on this subject matter and to these reviews.

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