Biogen

5 May 2020

Re: Biogen response to the European Commission White Paper on Artificial Intelligence: A European approach to excellence and trust

Biogen is one of the world's leading biotechnology companies, with a focus on discovering, developing, and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Founded in 1978, Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics, and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, immunology, neurocognitive disorders, acute neurology, and pain.

Biogen appreciates the opportunity to provide comments to the Commission consultation on the document "European Commission White Paper on Artificial Intelligence: A European approach to excellence and trust". Biogen would like to thank the Commission for seeking public input as part of the continued discussions regarding the European digital strategy.

GENERAL COMMENTS

A. **Commission vision**. Biogen appreciates that the Commission emphasized the potential impact of AI in health care as one of the primary drivers of the need for a European approach. In medicines discovery and development, AI can be used to identify promising compounds, aid in early detection of diseases for testing treatments, and potentially provide predictive analytics to identify safety risk or signs of efficacy sooner. Taken together AI has the potential to speed drug development, lower costs by focusing on the most promising candidates, and improve available treatments for patients in need. With this in mind, Biogen strongly supports the EU aim to become an economy that is "attractive, secure, and dynamic[ly] data-agile" by developing "a future regulatory framework for AI in Europe that will create a unique 'ecosystem of trust'."

B. **Proposed EU Governance Objectives**. We support the proposed objective of a European governance" in the form of a framework for cooperation of national competent authorities…to avoid fragmentation of responsibilities, [and] increase capacity in Member States". The intention to create a forum for exchange of information and best practices, and to issue guidance and opinion is sensible. In light of this, we strongly encourage the Commission to identify and communicate mechanisms to "maximum stakeholder participation" during development and implementation as proposed in the white paper.

SPECIFIC COMMENTS

A. **Public Sector Health care [Section 4.F].** Biogen acknowledges the Commission highlighting health care as a priority sector for developing an open and transparent action plan for the adoption of AI. In addition to the noted importance of hospitals and public administrations, there are many organizations that can contribute and benefit from the adoption of AI in the public sector. For example, the MHRA's Clinical Practice Research Datalink (CPRD) is a best practice model for data sharing for research today, although it is limited by access, data quality, and country participation. If the EU developed a common data model and improved access to all EU Member States data for research, it could enable improved disease understanding, real-world monitoring for safety of pharmaceutical products, and help to realize the vision for pragmatic clinical trials that are more representative of the patients who will eventually receive a medicine in clinical practice. Moreover, access to this type of data will allow for more training and subsequently improved accuracy for AI and machine learning tools that can benefit the public good.

B. **International Aspects [Section 4.H].** We are pleased to see the inclusion of multi-lateral engagement in this document including the call out to global players (e.g., OECD, UNESCO). We would recommend that for the focus on health care and medicines development, the Commission considers early future partnership with the World Health Organization (WHO), the International Council for Harmonisation (ICH), the International Medical Device Regulators Forum (IMDRF), and professional organizations like the Institute of Electrical and Electronics Engineers (IEEE), which is dedicated to advancing technology for the benefit of humanity.

C. **Regulatory Framework for AI [Section 5 Introduction].** Biogen is supportive of defining risk categories or criteria for AI systems that correlate with the anticipated level of regulatory oversight and requirements, similar to the IMDRF SaMD risk classification guidance, with additional external stakeholder input. This will create a framework that enables predictability in development and future investment.

   In addition, increasingly complex algorithms lead way to a new frontier for regulation: the 'black box' problem. Even if health authorities possessed unlimited resources and expertise, regulating AI by traditional means is impractical. Moreover, we acknowledge that changes and/or additions to the EU legal framework may be necessary to accommodate AI and machine learning, including 'unlocked' algorithms that change over time. As the Commission examines how regulations may need to evolve to suit these new technologies, we encourage policies that place an initial focus on sponsor governance and accountability to address the risks (e.g. protection of personal health data, data breaches) posed by the increasing role of AI in health care and drug development. Early regulatory approaches should focus on defining the risk, establishing procedures to address development, testing, and retesting algorithms, and governance to monitor performance and plan for proper risk mitigation.

Biogen acknowledges that transparency, traceability, and human oversight are critical areas that may not specifically be covered under existing health and pharmaceutical legislation. As the Commission and society's understanding of AI will progress rapidly the High-Level Group, in collaboration with external stakeholders, should incorporate a process of regular check-ins to incorporate new learnings and assess potential risks and mitigations, as it is impossible to identify all possible limitations at this stage.

D. **Product Safety Legislation [Section 5.B].** 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.