EFPIA responses to the European Approach for AI

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Overview

EFPIA applauds the Commission's effort to develop a European approach for AI that promotes Europe's innovation capacity in AI while supporting the development and uptake of ethical and trustworthy AI. The use of AI in healthcare is accelerating and as international regions outline similar goals, there is a need for both urgency and vision to establish Europe as a leader in AI. In conjunction with the European Strategy for Data, EFPIA recognises the need to create an environment that unlocks the value of the data and digital economy. EFPIA fully **embraces the potential benefits** which AI-powered solutions can bring to the healthcare ecosystem and its potential to positively impact the lives of patients and healthcare professionals. The Commission has rightly identified the need to foster ecosystems of excellence and trust in AI and we are committed to achieving these objectives as a valued partner.

The use of AI is becoming increasingly prevalent in healthcare because it has the potential to overcome some of the challenges in healthcare systems increasingly burdened with an ageing population, chronic diseases as well as budgetary and operational pressures. In this context, AI promises to provide better, faster and more customised care to patients, and for pharmaceutical companies to discover, develop and bring medicines to patients in a more precise manner. Whilst we must remain aware that our current human-reliant systems are not infallible, there are potential risks in the use of AI in healthcare such as potential injuries and error, privacy concerns, bias and inequality. This necessitates the education of stakeholders, whether they are patients, healthcare professionals or other users, and robust risk-assessment approaches to the introduction of new AI applications.

In order to achieve an ecosystem of excellence that supports the development and uptake of AI in healthcare, the Commission has proposed a series of measures. EFPIA considers more efficient cooperation between Member States and the Commission in the key areas outlined and reinforcing the skills agenda as the most important. EFPIA and its members are committed to achieving this ecosystem of excellence through our leadership in the Innovative Medicines Initiative (IMI) and our contribution of scientific and technical expertise.

The Commission has outlined positive steps towards building an ecosystem of trust in the White Paper, including the publication of the first draft of the Ethics Guidelines for Trustworthy AI by the High-Level Expert Group (HLEG) on AI. EFPIA emphasizes the importance of designing "human-in-the-loop" systems to combine the need for high accuracy of AI solutions and the flexible-problem solving capability of humans. As AI systems become more sophisticated, there will be a continuing need to ensure effective human oversight in line with the recommendations of the HLEG. AI systems should promote fairness and inclusion and avoid bias as well as provide transparency and enable accountability.

Healthcare is one of the most regulated industries with strict ethical and governance rules and evidence-based regulatory decision-making. To leverage the potential of AI in healthcare while protecting patient safety, a well-balanced, risk-based policy is crucial that reflects the benefits and risks of its application and fosters innovative uses and uptake of AI solutions to better serve patients.

As this important work proceeds, all stakeholders will benefit from a framework that is grounded in evidence and developed in consultation with them.

EFPIA's comments on the Commission White Paper

We call on decision-makers to consider the following points in the implementation of the European approach for AI to fully realize its potential and position Europe as a global leader:

- **Regulation should be adequate, appropriate, clear and non-contradicting:** Regulations on AI must be simple and clear in how and when to apply them, sufficient in their scope to regulate current and future potential uses without restricting innovation, non-overlapping/duplicative and fair and consistent in their application by stakeholders to keep a level playing field for all users. They are critical in building trustworthiness as AI use in making health decisions requires an appropriate framework and oversight to facilitate responsible AI.
- **Data Governance is fundamental:** GDPR is aimed at standardising and strengthening the protection of personal data, including the rights of individuals to be better informed about how their data are used. It also sets out clear responsibilities and obligations on healthcare professionals and companies using such data, with stringent penalties for infringements. GDPR requirements and concepts may require further clarification if they are to support innovation in AI. Furthermore, it will be important to address the fragmented application of the GDPR and other legislation bearing on scientific research across the EU.
- **Access to high-quality data is indispensable:** In order to assure high-quality AI solutions and to safeguard the EU's competitiveness in the international AI marketplace, the easy yet **compliant access to high-quality data** will be indispensable. This would help to reduce bias, discrimination and ensure the highest levels of safety and robustness of AI solutions in healthcare.
- **Accountability requires clarity:** As the provision of healthcare and citizen's daily lives are becoming increasingly more digital and the delivery of services may involve multiple entities, there needs to be more clarity on each party's accountability to obtain overall trust in the AI solutions as they are embedded in the healthcare ecosystem.
- **EFPIA supports a risk-based approach to AI:** Oversight of AI should be proportionate to the intended use and led by **defined risk categories** or criteria for the AI system. Regulators should review existing systems of risk-based regulation such as the risk categorisation principles for Software as a medical device from the International Medical Device Regulators Forum (MDRF), seeking additional external stakeholder input. This will create a predictable framework for AI development based on clear risk-based criteria, enabling future investment.
- **AI literacy is an enabler:** EFPIA views the **skills agenda** as being critical when it comes to AI in healthcare with a particular emphasis not only on healthcare professionals and patient communities to understand and utilise AI solutions but also policy and decision-makers to foster innovation. EFPIA supports partnerships between the public and private sectors, bringing together leadership and commitment from organisations to ensure coordination of research and innovation in AI. EFPIA members recognise through their accelerator and innovation hub initiatives that SMEs and academia are key components of innovation in AI, and that SMEs require both access to finance and support in the adoption of AI. Therefore, coordination of research centres of excellence and leadership from a lighthouse centre of research, innovation and expertise is critical to establishing European leadership in AI.
- **European policies must be set in the global context:** AI policies in Europe should take into consideration how they would apply internationally (e.g. an EU company with services abroad, a non-EU company with services in the EU). Local boundaries on technology are challenging,

implying that a more global approach will be required to fully achieve the goals. Any regulation should ensure an equal playing field for both local and global players while not stepping away from core European values.

- **Intellectual Property protection should be effective and predictable:** Effective and predictable Intellectual Property protection, including patents, is fundamental to advancing biopharmaceutical innovation, including AI. Intellectual property protections, including patents, provide incentives that drive and sustain those substantial investments in crucial prevention, treatments and cures, so they can be available to the patients who need them. Importantly, patents also promote the sharing of knowledge through the disclosure requirements of the patent system. As the Commission continues to consider the role that IP plays and, will play in the future, with respect to data, we encourage them to consider the many different types and sources of data that exist in today's complex technological environment. For example, while readily available data from public sources may not need or benefit from a system of incentives, other types of data that can only be generated through investment and great effort would not exist without incentive systems.
- **The evolving positive ecosystem of AI must be built together**: In concluding, EFPIA wishes to underline the importance of all key stakeholders being engaged in this initiative at the highest level and encourages early agreement on a **multi-stakeholder platform** to drive the proposal forward.