European Federation of Pharmaceutical Industries and Associations

EFPIA Position Paper on Artificial Intelligence

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Summary

Artificial Intelligence (AI) powered solutions have the potential to enhance the healthcare ecosystem. **EFPIA's vision is to maximise the potential of using AI to develop novel therapies and approaches to identify, treat and care for patients more efficiently, while preserving patient safety and privacy.** EFPIA inputs into ongoing policy debates suggesting recommendations on AI to ensure that they foster innovation while guaranteeing high healthcare standards and patient safety. This position paper contains key areas for consideration by legislators and regulators as they are developing a legislative framework on AI.

EFPIA fully embraces the benefits which AI powered solutions could bring to the healthcare ecosystem and its potential to positively impact the lives of patients and support healthcare professionals in delivering care. EFPIA supports **adaptation of existing frameworks for the acceptability in decision making and adoption of AI technologies** to provide a path through which AI can be developed, adopted and used in healthcare systems. The innovative biopharmaceutical industry recognises the current challenges faced by European health systems and aims to work with partners in achieving sustainable value-based and outcome-focused healthcare by leveraging opportunities provided by the increasing use of AI technologies.

EFPIA recommends the following aspects to be taken on board in future AI policy development:

- Rules on AI should be adequate, appropriate, clear and consistent, fostering a harmonised approach across the EU.
- AI literacy and competence building is an enabler.
- Access to high-quality data is critical to AI deployment.
- Data Governance is fundamental.
- Transparency should be defined in a way that it allows for sufficient interpretability or explainability of the AI and underlying data sets.
- Intellectual Property protection should be effective and predictable.
- Leadership and coordination are needed.

The EU has an opportunity to leverage its capabilities in healthcare by **accelerating the development of an AI ecosystem through inclusivity, capacity and trust.** EFPIA wishes to underline the importance of this agenda to the pharmaceutical industry and its commitment to contribute to its uptake and successful adoption.

EFPIA Position and Recommendations on AI

AI has the potential to make a significant difference to healthcare. A broad range of techniques can be used to create AI solutions to carry out or augment healthcare tasks that have until now been completed by humans or have not been possible previously. AI can bring significant **opportunities for keeping people healthy, improving care, saving lives and saving money for healthcare systems**. It can equip healthcare professionals (HCPs) with new tools to gain detailed data analyses delivered through the **generation of novel scientific insights** and allow them to dedicate more time to irreplaceable human interactions**.** AI will also provide an **automation of manual tasks to aid efficiency and standardization**. The boost in efficiency and efficacy strongly depends on the availability of data to train AI models and the adoption of AI in the healthcare sector. With appropriate support, patients will benefit from an **increase in evidence-based care, higher quality interactions with healthcare professionals and more personalized care plans**. Patients will be empowered to play an active role in managing their health and wellbeing that can save time and money. AI platforms also hold the potential to **design optimal drug combinations that are effective and based on real experimental data rather than mechanistic assumptions**[1]. AI platforms can also perform predictive modelling using data mining and probability to forecast or estimate more granular, specific scenarios or outcomes, this can be used to predict the benefits in combining specific drugs (combination therapies).

EFPIA believes there is a need for a common definition of AI in healthcare. There are many definitions of Artificial Intelligence (AI) with no general accepted definition. This position paper recognizes AI as it is described in the documents of the AI High-Level Expert Group (HLEG)[2] and considers 'AI as a problem-solving software and/or hardware used by humans to search for solutions by analysing the environment and taking actions – with some degree of autonomy'. Specifically, we use the term AI primarily to refer to '*computational modelling, such as statistical analyses, neural networks, data science, natural language processing and machine learning (including deep learning) all tools used by humans in furtherance to medicine development, diagnostic development, and patient care'.* This understanding is different from the colloquial, all-purpose nature of the term "artificial intelligence" that is used in general parlance. Most notably, our definition is not focused on so-called "artificial general intelligence," which is a different category of AI relating to self-aware, intelligent machines. The development of artificial general intelligence generally remains in the future and is not representative of the current use of AI by most companies and other healthcare organisations.

AI systems designed for use in the healthcare space need to be established through evidencable training, testing, and development that can demonstrate safe and efficacious outcomes with prospective validation. In regards to autonomous AI, the expectation around understanding decision making rationale should be consistent with what is currently required in the development of pharmaceutical drugs, biologics, medical devices, and other therapeutics.

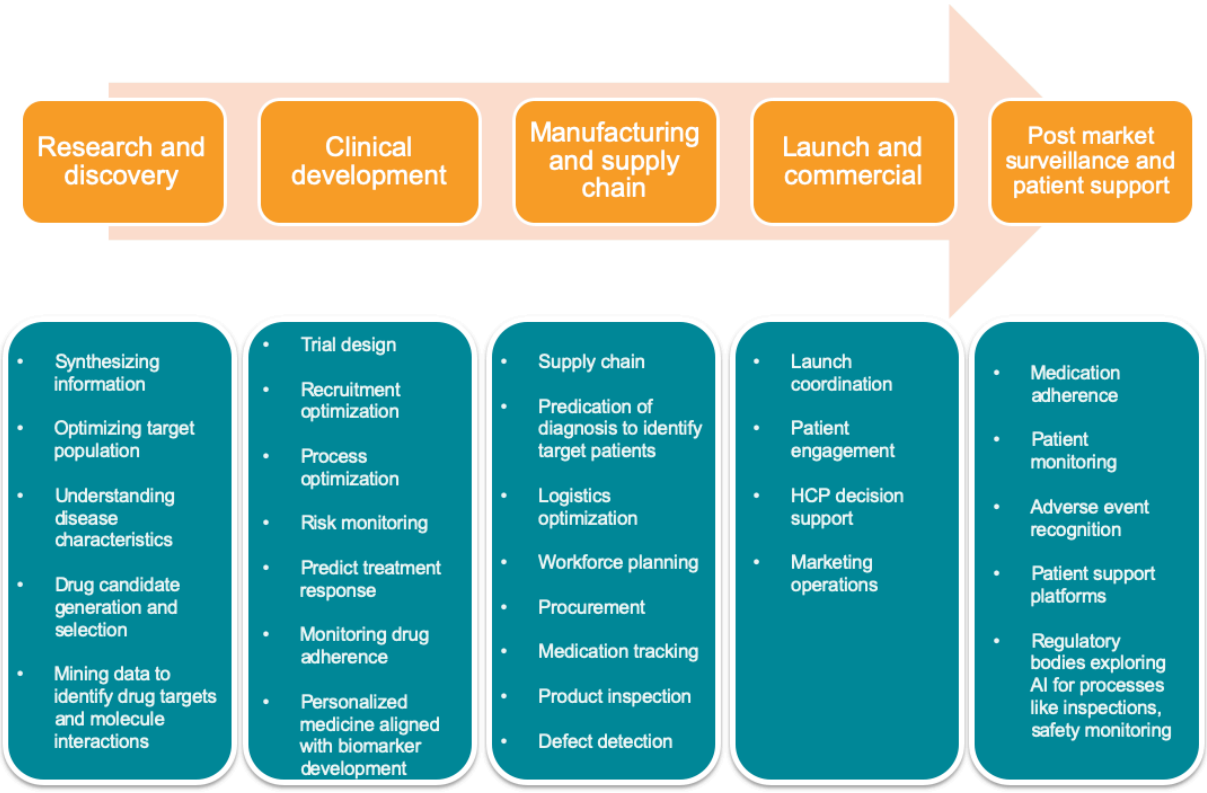
Importantly, patients and citizens should be central to the feedback loop and be empowered in the context of AI and digital technologies to build trust with patients and citizens and adjust to the needs of the users. **AI systems should promote fairness, inclusion and avoid bias as well as providing transparency and enabling accountability.** To support this setup there is a need to assess AI systems

[1] Mid-Term Review on the implementation of the Digital Single Market Strategy - A Connected Digital Single Market for All. SWD (2017) 155 final.
[2] https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai

to determine the appropriate level of human involvement in AI-augmented decision-making to ensure that appropriate oversight is embedded into business processes.

The aspiration to leverage AI technology for the benefit of patients cannot be considered without all the value-adding steps executed by different healthcare partners throughout the value chain. In particular, the innovative pharma industry uses AI for **discovering and developing novel therapies, personalised medicine (including biomarker development), improving diagnostics (through advanced machine learning for imaging), business optimisation, and engaging with and empowering patients and healthcare professionals.**

AI applications are being considered across the pharma value chain:



EFPIA supports a **sector-specific approach including a systematic assessment on which guidelines or regulations exist already and identify gaps or overlaps**. The innovative biopharmaceutical sector has considerable experience in defining good practice guidelines and implementing regulations to contribute to the development of an AI ecosystem in Europe. EFPIA offers to facilitate or participate in a series of discussions with pharmaceutical/healthcare/medical technology sector to formulate a forward-looking strategy to improve key aspects of drug discovery, patient care and healthcare delivery that could be enhanced with the use of AI.

EFPIA believes that the following principles and recommendations should guide the designing of an AI legislative framework:

1. Rules on AI should be adequate, appropriate, clear and consistent, fostering harmonised approach across the EU
   - Rules 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, align with global standards and ensure fair and consistent implementation by stakeholders to keep a level playing field for all operators. They are critical in building trustworthiness as AI used for health decision-making requires an appropriate oversight to facilitate responsible AI. Acknowledging that AI will present new legal challenges, we support a flexible regulatory framework that is effective whilst not being excessively prescriptive that it impedes innovation or affects negatively EU's competitiveness and position on the global stage. Given the speed of change in technological capabilities like AI, new approaches to existing guidance/regulations are needed to ensure that they remain robust as technology advances e.g. systems languages, total product lifecycle. Unclear regulation could create inconsistency in interpretation across the value chain e.g. divergent national interpretation of GDPR, and create confusion impeding wider application of AI. It will be important that the framework for AI use in healthcare is advanced globally across jurisdictions e.g. EU, US, Japan etc. to ensure similar frameworks are adopted.
   - **EFPIA supports adapting regulations rather than creating new rules**, providing clarification and guidelines, and exploring other mechanisms such as self-regulation. While it is essential to address any safety concerns, an unbalanced policy could lead to restriction of AI outside of its validated use and consequently leave patient benefits unexplored.
   - Continues engagement with the broad stakeholder base in policy development would inform outcomes proactively (e.g. use of regulatory sandboxes for testing, consortium-led data collaboratives to inform IT standards and open source protocols) and **ensure the development of an aligned EU AI ecosystem** (e.g. based on International Medical Device Regulators Forum principles and guidelines) that is **attractive to global innovators and is supportive of future advancements.**
   - EFPIA recognises the need for global regulatory alignment as part of a global approach and embrace existing legislation such as Medical Devices Regulation (MDR)[3]/In vitro Diagnostic Medical Devices Regulation (IVDR)[4]. EFPIA supports Commission's approach to **regulate AI based on risk,** acknowledging CE marking system for high risk applications in healthcare which is already addressed by MDR/IVDR.
   - There are many stakeholders involved in providing healthcare to citizens and increasingly these will be interconnected as an ecosystem, sometimes with AI solutions intertwined as a fundamental supporting tool and often instead of a human medical professional. Healthcare decisions can be significant and there is sometimes the need to clarify liability for decisions made. For the system to trust and rely on AI solutions embedded in the healthcare ecosystem there will need to have a clear guidance on liability and explicit transparency to patients in the role of AI in their treatment.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[4] https://eur-lex.europa.eu/eli/reg/2017/746/oj

2. AI literacy and competence building is an enabler
   - EFPIA views the **skills agenda** as being critical when it comes to AI in healthcare. **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.
   - It is important that healthcare professionals have the right skills to understand and utilise AI solutions and to have ability to exercise oversight in line with their mandate. There should be an educational focus on use of AI-based solutions for example in healthcare workforce's curricula and complementary courses as part of continuous professional development. Similarly, a focus on AI literacy for the broader society and skills by patient communities would also be warranted. **EFPIA calls for investments e.g. as part of EU4Health 2021-2027 programme, in reskilling and lifelong learning opportunities which are required to overcome social and cultural challenges affecting stakeholders in healthcare.**

3. Access to high-quality data is critical to AI deployment
   - 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 a significant amount of high-quality, representative data will be indispensable.** This would further help to reduce bias, discrimination and ensure highest levels of safety and robustness of AI solutions in healthcare. Patients and citizens should be empowered through feedback mechanisms to help address bias and other potential concerns. EFPIA supports initiatives which can provide for increased and appropriate access to high-quality health data, e.g. through the proposed EU Health Data Space. In particular, we encourage the Commission to **identify obstacles that would prevent an adequate use and deployment of AI in Europe through optimal data sharing between stakeholders in a data-agile economy and to explore appropriate standards, tools or frameworks to incentivize data sharing**[5] **such as for example Findata.**[6]

4. Data Governance is core
   - 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, local and institutional regulations, as well as ethical oversight, 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. It has to be ensured that data are managed and analysed within a secure and ethical governance framework.[7] Human involvement in AI-augmented decision making ensures that appropriate oversight is embedded into business processes.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX%3A52020DC0066, p. 13
[6] https://www.findata.fi/en/about-us/what-is-findata/
[7] https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/Big_Data/Final_-_Priority_Recommendations_of_the_HMA-EMA_joint_Big_Data_Task_Force.pdf

5. Transparency
   - The pharmaceutical industry has already embedded transparency in various aspects of its business. AI diagnostic tools and other patient-facing tools should be transparent around their function/training to some degree (or otherwise be independently tested for robustness), different approach should be applied in case of proprietary internal R&D tools, since the insights from those will be validated in conventional ways, e.g. animal studies and/or clinical trials.
   - Where transparency is more difficult, such as Artificial Neural Networks, transparency will need to be better defined in this context. **EFPIA recommends defining levels of transparency that allow sufficient interpretability or explainability of the AI and underlying data sets, including auditing mechanisms which are key to establish an environment of trust.** Control and retention of both the data sets used to train the model, and the code used to create the model would aid in transparency. It is also important that transparency requirements are carefully balanced to still allow sufficient incentivisation of the investments needed to stimulate the generation of the necessary data sets and AI solutions.

6. Intellectual Property (IP) protection on AI should be effective and predictable
   - Effective and predictable IP protection, including patents, is fundamental to advancing biopharmaceutical innovation, including with 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.
   - EFPIA encourages the Commission to consider the many different types and sources of data that exist in today's complex technological environment and consideration of how data evolves over time. 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.

7. Leadership and coordination
   - The private sector can explore the innovative uses of AI-based systems and inform the public data debate by demonstrating the value creation for the healthcare system, supporting its sustainability as well as the value creation to the European economy. The public sector will need to ensure that the right framework for engagement, the skills and infrastructure are present to leverage this and can bring significant human capital thanks to the education systems, workforce based on the skills agenda and capabilities through its investment in infrastructure.
   - **The European Commission must ensure this ecosystem is well-coordinated and the impact of the Coordinated Plan on AI with Member States is greater than the sum of its parts.** EFPIA welcomes the establishment of experts groups such as a High-Level Expert Group on artificial intelligence and calls for further development of guidelines fostering complementarity and synergies between national and EU level. The Coordinated Plan needs to demonstrate acceleration, clarity of ambition to attract private investment particularly from an international perspective, the right infrastructure and skills to make it attractive to develop an EU AI ecosystem, enabling the adoption of AI by the public sector, securing access and use of data, the right enablers and incentives for private investment. The Commission

need to ensure efficiencies are realised, clarity of guidelines and establish mechanisms for quick decision-making.

To conclude

EFPIA encourages further elaboration of EU plans on the development of a true centre of excellence for AI in healthcare, including policies on data and digital literacy within the healthcare sector and the general population, state supported investment programs, attractive "equal" partnerships between public healthcare systems and industry, testbeds for novel AI approaches and validation of AI systems and outcomes.

EFPIA asks the Commission **to adapt existing frameworks for the acceptability in decision making and adoption of AI technologies** to provide a path through which AI can be developed, adopted and implemented in healthcare systems. We would seek a greater clarity and guidelines that enable innovation, adoption and acceptance of AI technologies.

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 in a way that fosters cooperation amongst national competent authorities, avoids fragmentation and develops Member States AI capabilities.