Feedback provided by AstraZeneca:

Artificial intelligence – ethical and legal requirements

Introduction

AstraZeneca welcomes the proposed Regulation laying down harmonised rules artificial intelligence (Artificial Intelligence Act[1]) and believes that harmonised EU rules on AI can pre-empt a possible fragmentation of the single market and foster the safe and responsible development, use, and uptake of AI in the European Union. It. Below we provide initial feedback on the draft Act insofar as it is relevant for our business activities in biomedicine, pharmaceuticals, and healthcare.

Tightening the definition of 'AI' and 'Systems' to exclude legacy activities

The language used to define AI in the draft legislation is very broad and includes all statistical computations and analyses. Like many of its peers in the biomedical, pharmaceutical, and healthcare sector, AstraZeneca is a science- and data-driven business. AstraZeneca has routinely used the scientific method, statistical analyses, and computational methods for decades. Applications include biological discovery science, the enabling of clinical trials, interventional research, drug product approval, and post-marketing activities. The currently proposed inclusive definition of AI would encompass a large portion of the daily work of many biomedical and pharmaceutical companies. These activities were historically neither thought of or classed as 'AI' nor identified as conferring additional risks (often to the contrary).

As the draft AI Act will be following the normal legislative procedure, due consideration should be given to the potential cost of implementation for the private sector. In a recent report about How Much Will the Artificial Intelligence Act Cost Europe?[1], the Center for Data Innovation stressed that "the [AI Act] will cost the European economy €31 billion over the next five years and reduce AI investments by almost 20 percent. It is of paramount importance to define AI in a way that enables regulatory control where truly required for AI systems.

We would therefore appreciate further dialogue on a definition of AI that does not capture legacy activities and takes into consideration existing requirements in the field of diagnostics and medical products. Similarly, further guidance on the definition of a 'system' would be beneficial to data-driven industries to understand what activities are in and out of scope for this regulation.

AstraZeneca's AI applications

AstraZeneca invests in, develops, and uses AI technology. Examples of use cases include:

- **AI systems put into service for own use:** Many of our internal systems do indeed include machine learning, language processing, and decision assistance and automation using AI. The developers of our AI solutions are often also the end-users. Outputs of such AI systems might for example support patient stratification into clinical trials, or predictive algorithms to help design smarter trials.

- **Upstream use cases, where sector-specific processes or regulations mitigate risk:** This may for example include an AI modelling tool that predicts compound safety and efficacy prior to adding the compound to the company portfolio. This unvalidated compound still goes through safety

#

[1] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - https://ec.europa.eu/info/law/better-regulation/

exercises, clinical trials, in-depth analyses, and restrictions based on safety concerns, and regulatory approval. The potential risk generated by the use of an AI modelling tool is managed by the drug development process. Similarly, uses of AI tools in Operations is effectively mitigated through existing regulations such as Good Manufacturing Practices.

- **Medical software products developed using or containing AI:** In addition to manufacturing medicinal products, AstraZeneca is also a legal manufacturer of medical devices. We are increasingly exploring the potential benefits of the use of AI and machine learning technologies to enhance the medical device development process and indeed as a core component of the medical device itself. We have developed quality management systems for medical device design, development, and manufacturing and have recently endeavoured to supplement these systems with good machine learning practices. We, and our partners, follow IVDR MDR regulation for any devices supporting our medicines on market.

- **AI systems that support patient stratification** e.g. diagnostics

- **Facial Recognition** for employee and site security

Determining AI risk categories

The Commission proposal rightly highlights that the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes in the healthcare sector. AstraZeneca wholeheartedly supports the premise of the proposal that in the health sector where public health is paramount, AI supporting human decisions must be reliable and accurate.

The proposal lays down a risk methodology to define "high-risk" AI systems that pose significant risks to the health and safety or fundamental rights of persons. The European Council has called for a clear determination of those AI applications that should be considered high-risk. AstraZeneca supports this approach, as it ensures legal certainty and facilitates innovation and continued investments in AI technologies. We also strongly encourage a proportionate application of all relevant requirements proposed in the Act.

Our reading of the proposed Article 6 in conjunction with Annex II and Annex III of the draft Artificial Intelligence Act suggests a limited amount of AstraZeneca's current applications of AI would be categorised as high-risk, including the following:

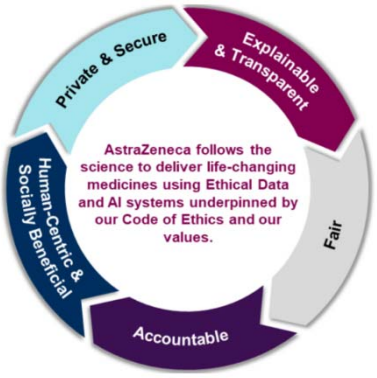
- Software as a medical device;
- AI systems acting as or supporting diagnostics (e.g. that support patient stratification); and
- AI systems used in facial recognition for employee and site, and information security.

Codes of Conduct

The draft Artificial Intelligence Act provides a framework for the creation of codes of conduct that encourages providers of non-high-risk AI systems to apply voluntarily the mandatory requirements for high-risk AI systems.

AstraZeneca develops and uses AI technology in line with its Principles for Ethical Data and AI (see Annex) as well as its Code of Ethics and Ethics & Transparency Commitment under its Sustainability Ambition.

AstraZeneca is furthermore committed to review its voluntary Principles for Ethical Data & AI against relevant requirements incorporated in the final Artificial Intelligence Act (gap analysis) and to promote the development of a sectorial Code of Conduct to this effect.



Annex

AstraZeneca Principles for Ethical Data and AI

Explainable and Transparent

We are open about the use, strengths and limitations of our data and AI systems.

- We explain to people if they are interacting with an AI system and whether interactions are recorded.
- We are able to explain when and how AI is used to aid a decision that impacts humans.
- We will ensure appropriate levels of explainability and transparency in line with our legal obligations.

We will ensure our assumptions are clear, we will ensure algorithms are appropriately documented, decisions are explainable as needed, and processes are in place to deal with unanticipated impacts.

- We can demonstrate our data sources, and how models are trained and maintained.
- We have the ability to explain processes, data and algorithms when required to do so while protecting our intellectual property.
- We are transparent about the use of AI to build trust and credibility in all our endeavours.

**Explainable refers to the ability of humans to understand the results of a solution generated by Artificial Intelligence*

Fair

We endeavour to use robust, inclusive datasets in our Data and AI systems.

- We seek to ensure our use of AI is sensitive to social, socio-geographic and socio-economic issues, and protect against discrimination or negative bias to the best of our ability.
- We will continually adapt and improve our AI systems and training methods to drive inclusiveness.

We treat people and communities fairly and equitably in the design, process, and outcome distribution of our AI systems.

- We are aware of the limits of our AI systems. We strive to apply their outputs in the right context and in a non-discriminatory fashion.
- We monitor our AI systems to maintain fairness throughout their lifecycle.
- We acknowledge all data sources and human effort in our Data and AI Systems, while protecting our intellectual property.

Accountable

We apply governance proportional to the impact and risk of our Data and AI Systems.

- We diligently assess risk against opportunities to act consistently with our company values.

We take accountability of our use of Data and AI Systems throughout their life cycle, so their use is appropriate and monitored over time.

- We anticipate and mitigate the impact of potential unfavourable consequences of AI through testing, governance, and procedures.

- We are accountable for our findings and the recommendations from AI systems. We govern AI-supported decisions appropriately.
- We recognise and address unforeseen consequences resulting from our AI usage appropriately, and ensure that lessons are learned.

Human-Centric and Socially Beneficial

Where Data and AI is involved, humans oversee the system and are accountable for driving clear, expected benefits to people and society.

- We apply AI to contribute to a sustainable workforce, business, and planet, to help make AstraZeneca a Great Place to Work, and accelerate our contribution to society.
- We involve people at appropriate times to responsibly deploy AI where decisions carry a material impact. We harness the capabilities of AI to accelerate the development and delivery of the right life-changing medicines to the right patients with the right commercial potential.
- We employ human-led governance over our AI systems. We respect human dignity and autonomy and strive to reflect this in our AI systems.

We drive prudent and sustainable energy consumption when using Data and AI systems.

- We recognise that protecting the environment is an integral part of ensuring AI systems are socially beneficial. We aim to reduce the energy consumption of our AI systems in line with our Ambition Zero Carbon.

Private and Secure

We respect privacy and control, and act in a manner compatible with intended data use.

- We respect privacy and the rights of all stakeholders, and will act in accordance with relevant laws and regulations.
- We assign appropriate protective measures to keep all information held or generated by AstraZeneca's AI systems secure.

We employ Data and AI systems that are designed to be secure.

- We strive to protect our AI systems against information breaches and unintended applications, with mitigation processes in place. We manage our AI systems through their life cycle, including information used and generated.

We review third party AI providers' data protection standards to seek alignment, and comply with applicable law.

+++ENDS+++