BIA policy submission

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UK BioIndustry Association

BIA response to Government Consultation on the Regulation of AI

Summary

The BioIndustry Association (BIA) welcomes the Government's commitment to crafting an effective regulatory framework for AI, focusing on key principles such as safety, security, transparency, fairness, accountability, and contestability. We strongly support the idea of empowering industry-specific regulators, like the MHRA, to create nuanced, context-specific regulations, addressing the unique applications of AI in the biotech sector.

Moreover, we suggest establishing regulatory sandboxes for testing AI systems and encourage a cyclical approach to regulation, keeping up with AI's rapid technological evolution. The introduction of additional tools such as ethical guidelines, evaluation frameworks, and data standards will also be beneficial in promoting responsible AI use.

Education for clinicians, researchers, and patients is paramount to mitigate overconfidence in AI tools and ensure their efficacious utilisation. National programs should reinforce technical scrutiny and competitive benchmarking of AI technologies and platforms.

The BIA and the life sciences sector are keen to partner in the development of best practice guidelines for AI applications in health, underlining that community and industry engagement is indispensable for effective regulation. Internationally, there is a strong need for alignment and interoperability with global partners, and we stand ready to contribute to establishing exemplary global AI standards.

By achieving these goals in a collective effort with the government, regulators, and other stakeholders, the UK can enhance its role as a global AI leader, driving growth, prosperity, and public trust in AI applications.

AI in the Life Science Sector

The BIA represents a growing industry of the future, one in which the UK truly leads the world. Our members are largely focused on developing new medicines and improving healthcare, but many are applying the power of biology to other challenges, such as replacing fossil fuels and feeding the world without environmentally-damaging, intensive agriculture.

Government figures show there are over 6,548 businesses in the UK life sciences industry, 70-80% of which are SMEs.[1] These businesses employ over 282,000 people and generated £94.2 billion of turnover in 2021. The number of businesses and the number of sites operated by these businesses have both seen an upward trend since 2009, with 23% more businesses and 32% more sites operating in 2021 compared to 2009.

As the trade association for innovative life science companies, the BIA recognises the transformative potential of AI in the biotech industry and healthcare, from drug discovery and development to improving patient outcomes, via early-stage detection and the prevention of disease. The use of AI-based tools has grown rapidly in the past decade to become one of the key drivers for discovering and developing innovative drugs and novel diagnostic tools in the biotech industry.

It is therefore critically important to build public trust and address the risks and concerns associated with the use of AI. The developing narrative about the societal risks posed by certain kinds of AI, such as the Large Language Models (LLMs) like ChatGPT should be explored in public debate with public and civil institutions ensuring this is done in an informed and evidence-based manner

AI is a very broad term encompassing many different types of programs. The AI used by the life science industry in general, and genomics companies in particular, is already highly regulated. They tend to be highly specialised and designed to perform very specific functions. They comprise Machine Learning such as Support Vector Machines and random forests (to identify patterns, make predictions, and classify data), Deep Learning (for DNA sequence analysis, predicting protein structure, or interpreting gene expression data), Natural Language Processing (to extract information from scientific literature and genomics databases), Genomic Variant Analysis (to aid in the interpretation of genetic variations), and Network Analysis (to identify key genes, pathways, or regulatory mechanisms associated with specific diseases or phenotypes). This is a rapidly evolving environment, and it is likely that LLMs will one day be used in the life science industry, for example to decipher the language of molecular biology (by having accurate *in silico* models of the primary biomolecular information highway — from DNA to gene expression to proteins).

The BIA supports the Government's approach to empower industry-specific regulators to develop a framework enabling the responsible application of AI and looks forward to engaging with government and with the Medicine and Healthcare products Regulatory Agency (MHRA) in designing and implementing industry-specific frameworks for the regulation of AI. The intended legitimate purpose of use of AI ought to be a key element for determining which regulatory framework is directly applicable.

[1] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021/bioscience-and-health-technology-sector-statistics-2021

Five Key Principles

The Government's focus on five key principles that will guide the responsible development and use of AI across all sectors of the economy: safety; security and robustness; appropriate transparency and explainability; fairness, accountability and governance; and contestability and redress is welcome.

The BIA also supports the Government's agile and iterative approach to developing the regulatory framework, which recognizes the speed at which these technologies are evolving and the need to have industry support in designing the framework. The MHRA will need to work closely with industry to ensure that it keeps up with the speed of evolution in this particular sector.

Clear and consistent regulation can support business investment and build confidence in innovation. It can provide industry with the certainty needed to make substantial investment decisions and agree on developmental pathways focused on the medium/long term.

The Government's proposal to issue the principles on a non-statutory basis and implement them by existing regulators, leveraging their domain-specific expertise to tailor the implementation of the principles to the specific context in which AI is used. AI is such a broad term encompassing very different applications, functions, models and sectors, there can be no ‘one size fits all’ approach to its regulation.

This approach should help to ensure that regulatory measures are proportionate to context, sector, and outcomes, by focusing on the application of AI rather than the technology itself.

Central Support Function

With regard to the central support function, the BIA welcomes the Government’s intention to ensure coordination and collaboration between different regulators and sectors, as well as its overall monitoring function. The central, overarching function will play an important part in the evolution of AI regulation.

While it is understandable that such a strategically important function should, at first, rest with central government, the BIA foresees that eventually such a function should rest with an arm’s length body, ensuring that the evolution of AI regulation is set on more permanent and politically neutral footing.

The BIA welcomes the Government's commitment to working collaboratively with regulators and taking an adaptable approach to evaluate the effectiveness of the framework and identify any barriers to its proportionate application, and looks forward to working with government and regulators to achieve those aims.

International alignment and interoperability

The BIA agrees that international alignment should support UK businesses to capitalize on global markets and protect UK citizens from cross-border harms. Life sciences is a global industry - both research and development (R&D), and drug sales and distribution occur across borders.

Similarly, many of the firms that currently create and deploy AI systems are international and AI systems are often deployed internationally. It is therefore crucial to ensure compatibility and interoperability with international partners whilst retaining any benefits derived from domestic regulatory flexibility.

This is a critical opportunity for the UK to lead the way and set the terms for global AI use, which in turn will help UK businesses and industry.

Additional tools

The BIA believes there is an array of additional tools which could complement the Government's approach to regulation. These could include:

- Tailored ethical guidelines and codes of conduct
- An evaluation framework - focusing on initial evidence of fitness for purpose, retrospective performance data in an independent coh
- ort and demonstration in a trial environment that it has patient, clinician and economic benefits - which should ensure that consistent standards are applied by the regulator
- The development of data standards and protocols to ensure interoperability and data sharing between different AI systems and platforms in the biotech industry
- Training and education programs to ensure that stakeholders in the biotech industry, including researchers, clinicians, regulators, and patients, have the skills and knowledge needed to effectively use and interact with AI systems

The BIA looks forward to engaging with regulators, industry, and government to develop these tools, standards, and programs.

Challenges for the industry

While many of the Biotech AI applications have high safety mechanisms (for example through the MHRA and the Medical Devices Regulation, the NHS Digital Health Technology Standards, GDPR, the Code of conduct for data-driven health and care technology, and the National Institute for Health and Care Excellence) there is a need to embed mechanisms to:

- encourage use of platforms with principled explanatory power and robust confidence levels for recommendations (with a description of the contextual evidence & information on which they are based)
- encourage and value recommendations based on causal principles rather than AI pattern-matching
- encourage testable (ideally provable) system designs based on AI frameworks that embrace these characteristics

Regulators

Regulators should collaborate with industry to build sandboxes to ensure the robustness of predictions can be evaluated over time. This would facilitate meaningful regulatory approval in a way that is consistent, adaptable, transparent to and achievable by innovators. The BIA recognises that this is a complex undertaking which will require close collaboration between regulators, industry, and the innovators of AI systems.

Because of the accelerating pace of innovation, there is a risk that regulators will lag behind the latest AI developments. The existing pace of competition-driven development and the volume of capital committed by industry means that these issues will have significant consequences in the very near future. Ensuring that regulatory bodies can attract sufficient skilled talent and have continual proactive engagement with communities, industry and innovators will be a key factor for success.

Training

Clinicians, researchers and patients must receive training to avoid over-confidence in LLMs and other AI tools, especially in the context of automating patient interactions and recommendations.

Universities teaching biomedicine should be encouraged to offer courses in Artificial Intelligence programming and ethics, as there currently a shortage of these skills in the UK.

National Programmes

All technologies and platforms included in national programmes must be subject to meaningful technical scrutiny and competitive benchmarking during design/procurement/use.

Tenders to provide services to government programmes should be open and transparent, with special regard paid to ensure equitable access for SME.

Guiding examples and best practice

There is a need for guiding principles and exemplars of best practice when it comes to health focused AI applications – technologists coming into the area do not necessarily understand the regulatory frameworks, ethical scrutiny and basic biological/clinical principles that should be considered when building solutions, nor is benchmarking against existing solutions easy. As AI models become more readily available, this problem will get worse.

The digital sandbox proposed by Sir Patrick Vallance will have to work exceptionally well to make an impact on this and the MHRA will need considerable support from the community to make this work. It would ideally also be supported by signposting from the community, incentives in the form of funding, and some level of accreditation for having passed scrutiny in the sandbox.

AI and liability

AI liability is highly complex, particularly in the life sciences sector where the technology is not only used in drug discovery, but increasingly in healthcare delivery. The Government's approach (to leave regulation of AI to existing sectoral legislative frameworks and regulators) is welcome, as it acknowledges the rapidly evolving nature of AI and the nuanced understanding these sectors have of their specific challenges. The Government's approach provides a contextually appropriate and flexible framework for regulation.

Life sciences already exist within a robust regulatory environment, and existing product liability and professional negligence laws have successfully accommodated many technological changes over the years. Therefore, while minor adjustments for AI might be necessary, drastic changes are not. It is also important to maintain technology-neutral product liability laws.

When considering supply chain AI risk, businesses typically use contracts alongside other measures to allocate liability between the entity placing a drug or device on the market (with which primary liability rests) and the other operators. Existing product liability laws are an essential context for negotiating these contracts and provide an underpinning set of principles of fairness and responsibility that enable those in the supply chain to allocate risk between them appropriately.

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Conclusion

The BIA is encouraged by the Government's commitment to create a clear regulatory framework for AI that prioritizes safety, security, robustness, transparency, fairness, accountability, and contestability.

The BIA strongly supports empowering industry-specific regulators, such as the MHRA, to develop nuanced, context-specific regulation to address the diverse applications of AI in the biotech industry.

The BIA supports the establishment of regulatory sandboxes for testing AI systems and encourages an iterative approach to developing regulations that keep pace with the rapid evolution of AI technologies. Developing additional tools such as ethical guidelines, evaluation frameworks, and data standards that can promote responsible use of AI is also important.
A dedicated focus on training for clinicians, researchers, and patients is essential to prevent overconfidence in AI tools and ensure the effective use of these technologies. National programs should enforce technical scrutiny and competitive benchmarking of AI technologies and platforms.

The BIA is eager to collaborate on the development of guidelines and exemplars of best practice for AI applications in health –community and industry engagement is a sine qua non condition in achieving effective regulation.

Alignment and interoperability with international partners are essential for a global industry like life sciences.

The BIA is committed to working with the Government, regulators, and other stakeholders in a unified effort towards responsible and innovative AI development in the biotech industry. By achieving these aims, the UK can strengthen its position as a global leader in AI, driving growth, prosperity, and public trust in AI applications.

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

For any further information on the contents of this submission please contact the BIA policy team at