ABHI Response to the Consultation from Department of Culture Media and Sport on "Data. A new Direction"

Introduction

Thank you for the opportunity to provide feedback on the above consultation.

The Association of British HealthTech Industries (ABHI) represents a diverse range of companies with an interest in health, care and wellness data for a broad range of purposes such as clinical trials, research and development, algorithm training & validation and post market surveillance. Many of today's medical technologies rely on personal data to deliver diagnosis or treatment, data is also a critical component of the safety regime. Appropriate access to data for regulators, users and developers is necessary to ensure delivery of safe and effective technologies and their safe implementation within a health, care or wellness context.

There are 5 broad principles that we consider important to the development of the regulatory regime.

- **Globalisation**: should align with international approaches for data regulation and be underpinned by appropriate international standards, in particular it should maintain adequacy with EU GDPR
- **Realistic & Equitable**: regulation should be proportionate and appropriate responding to the risk profile of the data activity
- **Agile**: frameworks should not be unnecessarily burdensome and facilitate quick and appropriate decision making,; they should align and utilise appropriate sectoral regulatory regimes
- **Creativity**: utilise legislation sparingly and support innovative use of standards and guidance within current frameworks.
- **Transparency**: the process should have clear scope, guidance, processes and standards;

For the medical technology industry, the secondary use of health data for research & innovation may lead to insights and solutions in medical science and deliver benefits for humankind. The pace of the digital transformation and innovation in the development of new treatments is highly dependent on the medical technology industry's ability to successfully access, aggregate and appropriately use health data.

There is a vast potential for data to improve healthcare and fuel economic growth and ensuring that data is able to flow freely across the health and care environment is vital.

Collecting, managing and using diverse data flows effectively presents us with the opportunity to reshape how citizen and patients interact with the health and care system, how services are delivered and provide improved delivery efficiencies. However, the increased use of data and digital technology also raises important questions around issues such as transparency, privacy, trust, inequalities and bias.

Within the health context, regulation needs to focus on ensuring that healthcare professionals and patients gain or maintain timely access to high-quality, safe and effective digital health products and services, while ensuring that ethical and data protection considerations are taken into account.

Further regulation has as an important role to play in demonstrating to public and users the trustworthiness of the system to build confidence in the use of their data.

It is important to consider the implementation of data regulation in the context of the wider regulatory landscape for deployment of data driven health services and need to look at alignment of product, clinical service, and data regulation.

We also need to consider the global nature of the health technology industry and the inherent need for cross border data flows.

Outlined below are some key areas that impact on our sector, we have also completed relevant section of the on-line consultation in more detail. Our responses are presented in the health and care context outlined above and from the perspective of developers on digital health solutions that access and work with data provided by patients, public and health & care systems:

Research Purposes

We appreciate that the Consultation supports clarifying a broad meaning for the term "research," as suggested by the UK GDPR recitals. The advance of research in medical technology would benefit from clarity and legal certainty that the "research" provisions of the UK GDPR apply equally to private and public research projects.

The definition explicitly should include research by private parties, especially where private parties perform research in accordance with related sector-specific methodological and ethical standards. It is important for the definition and scope of "research" under UK GDPR go beyond formal clinical studies to also include research on real-world evidence and secondary use of clinical trials data. These sources and uses are increasingly important to medical technology development, and their use both speeds and improves the quality of research purposes. Lastly, the definition and scope of "research" should also support the legal obligation of medical technology companies to engage in pre- and post-market clinical investigations and studies, which require the collection and processing of sensitive data. Additionally, MedTech companies have specific obligations regarding vigilance and safety reporting. This would require a broader interpretation of research than currently defined.

Some of the issues MedTech companies face have their origin in the lack of certainty around the appropriate legal basis and condition for processing and that UK GDPR requirements are not always consistent the medical device regulations and work to align sector-specific regulation (UKCA mark for medical devices and invitro diagnostics) would be beneficial.

The UK GDPR acknowledges the special position of research, by acknowledging the compatibility of further processing for research purposes, and the tempering of certain data subject rights when data is processed for research purposes.

We welcome the proposal for legislation to make data anonymous relative to the means available to the data controller to re-identify it. Further work is required to clear define and explain the terminology and potential uses cases regarding "anonymisation", "anonymous data", "de-identified data" and "secondary use" and when a data set can be considered sufficiently anonymised so it can be used and shared for commercial scientific research by MedTech companies.

Legitimate Interests

We support the establishment of a list of legitimate interests for which no balancing test would be required, this would substantially support innovation and the development and use of medical technology in the UK. It is critical that mechanisms exist to keep this list contemporary so as not to limit future. We also believe that there may be an opportunity to provide sector-specific legitimate interests, in addition to the general menu available to all. We are of the opinion that the concept of such a list should not exclude a broad framing of legitimate interest to not to limit future applications and rely on relevant safeguards.

AI and Machine Learning

ABHI supports the UK Government's objective to clarify fundamental principles for AI in horizontal regulation applying to all industry sectors such as the UK GDPR, especially in relation to requirements around accountability, transparency, fairness, and security in AI.

In parallel, ABHI recommends adopting a risk-based and sector-specific approach to regulation and guidance to ensure there is legal certainty on how those fundamental principles apply to specific, already well-regulated sectors such as medical technology.

For medical technology, the existing medical device regulatory framework administered by the Medicines and Healthcare Products Regulatory Agency (MHRA) already sets out precise requirements for medical device software, including those incorporating AI or Machine Leaning (ML) features. The MHRA regulatory framework – rather than a broad horizontal AI regulation -- is the best means to address issues related to the use of AI in medical devices, because it is contextual and would avoid potential legal confusion or lack of certainty for medical device innovators that could arise from any competing MHRA and horizontal AI legal principles.

Fairness

ABHI agrees that definition of "outcome fairness" needs to be clarified and recommends leveraging MHRA regulations to assess outcomes fairness in light of the existing extensive framework and enforcement mechanisms for the safety and performance of medical technologies, including those medical technologies that comprise, or incorporate AI. This existing framework is best placed to determine how the concept of "outcome fairness" applies to the medical technology industry, and the necessary regulatory requirements that need to be set out in that regard.

Bias and Discrimination

ABHI shares the view that making explicit consent a prerequisite for data access and use for bias detection and mitigation purposes may in itself risk introducing bias into the data used in an AI system, furthering the risk of introducing unwarranted bias in AI algorithms used in medical technology, and supports the Government

Automated Decision-Making

We would support the Taskforce on Innovation, Growth and Regulatory Reform's recommendation that Article 22 of UK GDPR be removed, and that the use of solely automated AI systems be permitted on the basis of legitimate interests or public interests, subject to appropriate sectorial regulations, including ensuring AI is free of biases and profiling.

The use of solely automated AI systems should be permitted on the basis of legitimate interests or public interests, subject to appropriate sectorial regulations as laid out in existing medical device and invitro diagnostics regulations which already require that manufacturers of medical devices (including those AI-enabled) demonstrate the safety and performance of their devices considering its intended use.

Data Minimisation and Anonymisation

We strongly support the proposal for legislation to make data anonymous relative to the means available to the data controller to re-identify.

We have concerns that some of the proposals outlined in this section, such as the introduction of fee regime, we recommend that it is further investigated to what extent this may put at risk the current adequacy agreement with the EU. This adequacy agreement is an important mechanism for data sharing for our sector.

Intermediaries

We support the creation of data intermediaries (such as Trusted Research Environments) in particular for data hosted by public bodies, such as the NHS. We are in favour of fair access terms that are not discriminatory between requests from public sector versus private sector.

Boosting trade and reducing barriers to data flows

We welcome the Consultation's recognition of the importance of cross-border data flows. We support the UK's proposed risk-based approach to international data transfers, governed by pragmatism and effectiveness. At a time of rising protectionism across the world, the UK should continue to promote strong privacy safeguards and international data flows as pillars of the data economy. The UK should also be a strong voice against localization trends and other restrictions to international data flows.

Personal Data Use in the COVID-19 Pandemic

The proposals to enable private companies, organisations and individuals processing personal data for a public body to be permitted to rely on that body's lawful ground for processing the data are supported, but they do raise important considerations for the private sector entity regarding how they would receive assurance that the public body had appropriately assessed the lawful ground. We would like clarity on how the private sector entity be impacted if the public body was found by ICO to have erred in its assessment.

As an additional safeguard there should be a written contract in place between the public sector and the private company.

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