Response to ICO consultation on how organisations can continue to protect people's personal data when it's transferred outside of the UK

7 October 2021

Introduction

ABHI welcomes the opportunity to provide comment on the ICO consultation on how organisations can continue to protect people's personal data when it's transferred outside of the UK ("the Consultation") from the view of the HealthTech sector. ABHI is the UK's leading industry association for health technology (HealthTech) with members, including both multinationals and small and medium sized enterprises (SMEs), supplying products from syringes and wound dressings to surgical robots and digitally enhanced technologies. Increasingly These products and solutions rely on the collection, analysis, and sharing of health data, which is by nature personal data,

HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is now the largest employer in the broader Life Sciences sector, employing 131,800 people in 4,060 companies, with a combined turnover of £25.6bn.

General Comments

We welcome the ICO recognition of the importance of international data flows. The continued ability to transfer smoothly patient-related data between the United Kingdom (UK) and other jurisdictions, is critical to the research and development of new technologies, monitoring the safety and effectiveness of existing products on the market, and providing support services for health technologies currently in use.

We support the following broad principles in future developments of the UK GDPR legislation

- Maintains alignment with key trading blocs such as the European Union (EU) and North America
- Provides regulatory clarity
- Facilitates international data transfers
- Maintains high standards of data protection, trust and confidence
- A proportionate and risk-based regime

There is an opportunity within these broad principles to avoid fragmentation between international legal frameworks whilst enabling UK business to have a streamlined regulatory that reduces bureaucracy and supports growth.

Transfer Risk Assessment (Q9)

There are a number of positive aspects to the proposals:

- Useful examples of what may be regarded as low, medium and high risks.
- Clarity that exporters don't have to look for identical legal systems and that diversity in approach is welcomed.
- Accessible scenarios in the TRA showing when transfers may be permitted.
- Holistic approach to assessing risk
- Recognition by the ICO that conducting a TRA can be challenging and that an organisation undertaking 'best efforts' to complete the TRA will be taken this into account in any regulatory action.

The TRA appears cumbersome to use and we would suggest that the ICO investigated the possibility of creating an interactive tool.

Example transfer scenarios for the HealthTech industry (Q10)

1. **Research and development of medical technologies**
   To ensure that new medical technologies are safe and effective, data are needed from clinical studies that evaluate the use of the new product in patients. Increasingly, cross-border clinical are organised to ensure that new products are safe and effective across different demographics, and it is more efficient to find a representative sample of trial subjects when you can conduct trials in different countries.
2. **Demonstrating safety and efficiency**
   The data that is generated during global research and development (R&D) must be analysed by experts and used in submissions to health authorities and other oversight bodies worldwide. These submissions are critical to demonstrating that new medical technologies are safe and effective for their intended uses. Regulators and oversight bodies must receive data that allows links back to the original study – without those links, regulators would not be able to have confidence in the scientific integrity of the research.
3. **Monitoring and reporting**
   Once the product is on the market, manufacturers have legal and ethical duties to monitor the use of their products and to analyse events and report safety issues to authorities. To meet these responsibilities, companies must be able to collect information on adverse events, wherever they occur, and share this information with all relevant oversight bodies wherever the product is marketed. That way, patients in every country get the benefit of a manufacturer's global experience with their product.
4. **Seamless healthcare delivery**
   Just as companies need to be able to transfer data across borders to conduct R&D and monitor product safety, healthcare delivery often also involves data transfers. Modern healthcare delivery relies on the availability and performance of a multitude of medical technologies. These devices are increasingly interconnected and must work seamlessly together to provide healthcare professionals with the diagnostic, therapeutic, and preventive tools they need to deliver high-quality, life-saving medical care. These medical technologies may transmit data to a centralized, global platform that can be accessed by health care providers and allows for real-time healthcare monitoring. They may also be supported by a team of global service provider personnel to ensure continuity of operations and optimal performance.
5. **Remote patient monitoring**
   Remote patient monitoring technologies have been shown to be effective in managing chronic disease and post-acute care. They can provide health care professionals with information to enable early detection of health events so that proactive interventions can be prescribed. They can also be used to alert caregivers to situations requiring immediate medical attention. Many medical devices on the market today come with remote communication abilities embedded or available as optional attachments. A central database may be used to cost-effectively provide remote patient monitoring services to health care providers around the world.
6. **Remote service**
   Remote service is the delivery of hardware and/or software system support, maintenance, and troubleshooting from a location beyond the healthcare delivery organization's site. Remote servicing capability has become common for most IT-based medical equipment. Remote servicing allows an equipment service provider to more efficiently monitor system performance and perform maintenance, enabling early detection and correction of potential hardware and/or software problems that could jeopardize the correct operation or continued availability of the device. It also allows remote service technicians, in the event of a system failure, to assess the severity of the problem and determine possible solutions. This can be critical when a failure occurs during a medical procedure and the healthcare provider requires immediate assistance. Finally, it enables service provider staff to more effectively provide support information and advice when on-site visits are costly or impractical.

7. **Patient-Customized Treatments**
   Life science products increasingly require sharing and using patient data so that treatments can be customised to particular patients. From sizing of a prosthesis to tailored therapeutics, there is an ongoing need to exchange patient information so as to optimise healthcare delivery.

International data transfer agreement (Q11)

We welcome many aspects of the proposed UK international data transfer agreement:

- The tabular approach and ability to edit this of the appears to make it flexible and easy to use.
- 'one size fits all' type agreement is welcome rather than the modular structure of the EU SCCs.
- Flexibility in the application of clauses based on status of parties
- Option to make the agreement multiparty and recognition that parties may have linked agreements (a master service agreement or data processing agreement) and ability to cross-reference these. This could be supported by a template for a formal version.

However we are concerned that the IDTA says its provisions and the associated transfer risk assessment should be reviewed annually; this could be excessive for low-risk transfers. Also for controller-to-controller transfers, data subject rights are extended to include an obligation to comply with "any reasonable request" of the data subject which is too open ended.

At present we have no insight into which countries or regions will accept the IDTA, once implemented country specific guidance from the ICO would be welcome.

SCCs (Q13 & Q14)

We support the proposals to to adopt model data transfer agreements issued in other jurisdictions and urge the ICO to validate the use of the European Commission SCCs. The inclusion of the draft addendum to the EU SCC's is welcome as this will modify parts of the EU SCCs that refer to EU or member state law or to EU or member state institutions so the clauses can be used for data transfers from the U.K. It is good that the addendum is short, clear and flexible allowing its terms to be modified so long as appropriate safeguards are maintained. The value in the addendum is that it removes complexity and cost for organisations and the need for preparing different forms of language for the EU and UK transfers.

However, we are concerned that the ICO may impose a specific form to do so, namely the UK GDPR addendum to the European Commission SCCs: companies should be free to make the necessary adaptations (as listed in the addendum) in the form they deem appropriate. The ICO should consider adopting the same approach as the FDPIC in this respect.

Adopting model data transfer agreements issued in other jurisdictions is vital to help reduce fragmentation and avoid international companies needing to comply with different obligations (like potentially different sets of Standard Contractual Clauses). This in turn enables UK businesses to have a streamlined regulatory approach that reduces bureaucracy and supports growth should a company seek to expand its business outside the UK.

Conclusion

There are many positive aspects to the proposals and we are generally supportive. We would urge that policymakers and the ICO recognise the importance of continued data transfer in health care between the UK and other key trading partners such as the EU and US. These essential activities should not be disrupted by the creation of diverging international data transfer frameworks that result in different obligations for companies seeking to expand their business outside of the UK. In addition, the broad material and territorial scope of the EU GDPR makes it increasingly difficult to escape its regime resulting in many UK businesses automatically falling into its scope.

Contact

Andrew Davies, Digital Health Lead
andrew.davies@abhi.org.uk

Association of British HealthTech Industries
Suite 2, 4th Floor, 1 Duchess Street, London, W1W 6AN