Innovation Without Borders:
The Importance of Transatlantic Data Flows to Healthcare Innovation and Delivery

Discussion Paper

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The judgment of the Court of Justice of the European Union ("CJEU") in *Data Protection Commissioner v. Facebook Ireland Limited, Maximillian Schrems* (C-311/18) (the "Schrems II" case) has created legal uncertainty around the future of international transfers of personal data from the European Union to the United States and other third countries. There is a risk that data protection authorities across Europe will interpret and enforce the judgment differently and that some authorities might order the suspension of certain transfers.

The suspension of data transfers critically needed by pharmaceutical and medical device companies would have serious consequences impacting both healthcare innovation and healthcare delivery. These activities would be made more difficult at a time when healthcare systems are already under tremendous stresses due to the COVID-19 pandemic. Thus, while *Schrems II* has created many uncertainties, one thing *is* certain — **patient care will suffer if life sciences companies lose the ability to transfer personal data from the EU to US.**

The transfer of data between the EU and the US for pharmaceutical and medical device development and support purposes serves the public interest in the protection of human health. These data transfers are crucial to continued delivery of life-saving health care services and innovation to address unmet medical needs. Numerous safeguards ensure that the data transferred is used only for permissible purposes. And importantly, there is no reason to believe these transfers pose any of the risks to privacy that were of concern in the European Court of Justice *Schrems II* judgment.

The undersigned organizations urge that policymakers and data protection authorities understand the importance of continued data transfer in health care between the United States and Europe and work to ensure that these essential activities are not disrupted while revisions are adopted or a successor is developed to the EU-U.S. Privacy Shield Framework.

Data Transfers Between the United States and Europe

The continued ability to transfer patient-related data between the United States and Europe is critical to the research and development of new medical products, monitoring the safety and effectiveness of existing marketed products, and providing support services for medical technologies currently in use. These important and necessary data flows go in both directions, and patient care will inevitably – and needlessly – suffer if restrictions on transatlantic data transfers are imposed without due consideration of the facts and circumstances of each type of data transfer.

In order to be able to effectively and efficiently develop, manufacture, and distribute drugs and medical technologies, life science companies need to be able to operate and collaborate on a global scale. Beyond the need to transfer patient data, pharmaceutical and medical device companies that operate globally need to be able to transfer a range of data concerning health care professionals, researchers, support technicians, employees, and others. The continuity of R&D and healthcare services provided by the global pharmaceutical and medical device industries depends upon these transfers. Any abrupt changes to the ability of these companies to transfer data outside of the EU will have significant operational impacts.

The European Court of Justice in its recent judgment in *Schrems II* expressed concern that certain US laws – namely the Foreign Intelligence Surveillance Act (FISA) and Executive Order 12333 – may authorize government agencies to compel the disclosure of data transferred from the EU to recipients in the US. While these laws may authorize US government agencies to obtain access to communications exchanged by or between individuals who are the target of US foreign surveillance, there are no reported cases of these laws having ever been used to obtain data transferred for pharmaceutical or medical device R&D or service delivery. In fact, there is no reason to believe that these data flows present the types of risks to privacy that were of concern to the European Court of Justice:

- **Clinical Study Data:** Clinical study data is key-coded at the study site and reported to the study sponsor (i.e., the pharmaceutical or medical device company who is undertaking the research) in this key-coded form. Key-coding involves replacing all direct identifiers with a subject identification code that is maintained confidentially at the study site. Key-coded clinical study data does not contain any of the identifiers that are used by US intelligence agencies to identify communications of foreign intelligence interest (e.g. name, address, phone number, email address, etc.). The European Data Protection Board (EDPB) has recognized pseudonymization of data as an effective means to ensure that data transferred from the EU to other jurisdictions continues to be protected in accordance with EU requirements.

- **Product Safety Data:** Reports of product adverse events are typically triaged on a country or regional basis. Only minimal information is then transferred globally for purposes of case analysis and reporting to health authorities. Directly identifiable patient information is rarely transferred.

- **Patient Monitoring, Product Customization, and Product Support Data:** Medical technology companies in Europe and the US take extensive steps to safeguard patient data from inappropriate access. These safeguards typically include the use of encryption and strong authentication requirements for user access. There is rarely a need to transfer directly identifiable patient information while providing remote device support. Patient monitoring and product customization services may require the transfer of more directly identifiable information, but patients are informed and, if applicable, must agree to these transfers.

From Research & Development to Product Safety

Today's pressing health concerns require global, concerted efforts to find safe and effective solutions. The COVID-19 global pandemic has highlighted the importance of global cooperation to address the threats posed to life, well-being, and economic prosperity by diseases and pathogens. Through data sharing and collaborative research, biopharmaceutical and medical technology companies worldwide are racing to develop treatments for the COVID-19 virus and vaccines to limit its spread. Right now, there is an acute need to transfer data around the world to speed the discovery and development of new life-saving and life-enhancing medical products. But this need did not start with the current pandemic and will continue long after it ends.

Global clinical studies

Development of innovative products to treat and prevent serious health conditions and diseases takes years. Products that must be effective worldwide require the input of scientists worldwide. To ensure that new medical products are safe and effective, data are needed from clinical studies that evaluate the use of the new product in patients. Increasingly, clinical studies involve patients and sites worldwide. Why? Global studies 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 around the globe. This is especially true for studies involving rare diseases and conditions.

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 therapies are safe and effective for their intended uses. Regulators and oversight bodies must receive data that allows links back to the original trial – without those links, regulators would not be able to have confidence in the scientific integrity of the research.

Monitoring and reporting

Finally, regulators and drug manufacturers still need data after a product receives clearance or is approved for marketing. Medicines agencies are charged with ensuring that the drugs and devices used to treat their citizens are safe and effective, and manufacturers of drugs and medical devices have legal and ethical duties to monitor the use of their products in real-world clinical practice 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.

From Patient Monitoring to Product Maintenance & Support to Product Customization

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.

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.

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. Maintenance and support of today's highly sophisticated medical devices requires specialized knowledge and training, and a global team of support professionals can most cost-effectively provide this support on a 24/7 basis.

Patient-Customized Treatments

Life science products increasingly require sharing and using patient data so that treatments can be customized to particular patients. From sizing of a prosthesis to tailored therapeutics, there is an ongoing need to exchange patient information so as to optimize healthcare delivery.

Conclusion

The life science industry in the EU and the US is committed to the highest legal and ethical standards for handling health data and reckons that the concerns of the European Court of Justice Schrems II judgment do not apply to the transfers of health data from the EU to the US. The signing organizations would like to re-iterate the importance of the seamless continuation of health data transfers between the EU and the US for the interest on patient safety and uninterrupted healthcare delivery until revisions are adopted or a successor is developed to the EU-U.S. Privacy Shield Framework.

We remain at the respective authorities' disposal for any possible questions.

About AdvaMed

The Advanced Medical Technology Association (AdvaMed) is a trade association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers.

For more information, visit www.advamed.org.

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

For more information, visit www.efpia.eu.

About IPMPC

the International Pharmaceutical & Medical Device Privacy Consortium (IPMPC) is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers. The IPMPC strives to be a leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.

For more information, visit www.ipmpc.org.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.