

OPEN LETTER

Brussels, 1 October 2020

Subject: Implications of the ECJ decision on the “Shrems II” for international sharing of health data for research

Dear Commissioner Reynders,

We write to you in our capacity as co-chairs of the joint European Academy networks, ALLEA, EASAC and FEAM, project “International sharing of personal health data for research” to express our concern at recent developments relating to the General Data Protection Regulation (GDPR).

Our academies are committed to the objectives of sharing personal health data for research, while ensuring privacy, for the benefit of both current and future patients. The GDPR is a critically important framework for the safe sharing of such data but it has become apparent that there are major problems for the international transfer of data from the EU/EEA to other (“third”) countries. These issues are being examined in our current joint academies’ project (for further details see, for example, <https://easac.eu/projects/details/international-transfer-of-health-data-for-research/>). Our project secretariat had useful, earlier discussion with your colleague leading the policy effort in DG Justice, and by the end of 2020 we will finalise our report to provide guidance to the European Commission on the range of data sharing issues facing researchers in the public sector.

However, the urgency is increased by the recent judgement of the European Court of Justice (case C-311/18, 16 July 2020, “Schrems II”) where additional concerns for researchers are raised by the invalidation of the Privacy Shield mechanism and by the emergence of new uncertainties on the standard contractual clauses (SCCs) for the transfer of personal data to third countries. While general reaction to this recent European Court of Justice decision has focused on the implications for the commercial sector, we now wish to express our growing worry about the consequences for public health research and for the patients and citizens who benefit from this research. The importance of international sharing of data for research has recently been exemplified by the challenges in responding to COVID-19. It is essential that policy makers and the European Data Protection Board (EDPB) understand the considerable value of health research in Europe that may be lost unless mechanisms facilitating international sharing of personal health data with public sector institutions are clarified and supported.

Currently, there are no clear and implementable guidelines on existing/previous transfers of pseudonymised research data that were shared by public sector researchers using SCCs or on what technical and organisational measures would now be deemed satisfactory. The

uncertainties and difficulties in operating the GDPR are affecting many research institutions and clinical research projects across Europe.

We take this opportunity to emphasise that:

- International public sector medical research has considerable value for patients.
- Health data must be shared safely and effectively while protecting patient privacy.
- Under the current provisions of the GDPR, sharing data with public sector researchers outside the EU/EEA does not work well.
- The uncertainties and problems for researchers in Europe, including those relating to existing data transfer using SCCs, have been exacerbated by the recent European Court of Justice decision.
- There is now urgent need for clear and implementable guidelines on appropriate safeguards.

We very much hope that you will be able to advise us on the European Commission's timetable for resolving these problems. We, with our expert colleagues, stand ready to help you and the EDPB in developing the appropriate policy and practical guidelines and we would welcome the opportunity to discuss these points further with you and your colleagues.

With best wishes,



Volker ter Meulen
Chairman of EASAC Biosciences Programme



George Griffin
FEAM President

Co-chairs of the ALLEA-EASAC-FEAM project Working Group

Cc:

Stella Kyriakides, Health and Food Safety Commissioner;

Mariya Gabriel, Innovation, Research, Culture, Education and Youth Commissioner;

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