European Alliance for Personalised Medicine

Members Update: Discussion in the ENVI Committee on the Data Protection Legislation

Brussels, June 6th: During this week, EAPM has being contact with our members to identify our key concerns on the debate in the European Parliament around the Data Protection Proposal.

As mentioned in the EAPM Members update of March 8th, there was over 4000 parliamentary amendments proposed by different stakeholders. Accordingly, we wanted to ensure that our key priorities of our members were highlighted from the patients, medicial professional, researchers, scientific stakeholders, healthcare planners and industry.

In this context, EAPM supports its members in the following points in relation to the following issues in the context of these amendments:

Processing for historical, statistical and scientific research purposes: EAPM supports the clarification that further processing of personal data for research is not incompatible with the Regulation, as introduced by AMs 821, 3062, 3065, 3069 and 3084.

On other hand, EAPM strongly opposes:

- AM 27 - **Processing of health data** for medical research purposes are critical to discovery and development of new treatments and diagnostics. Medical innovation will be negatively impacted by this amendment.

- AMs 327 and 328. The purpose of Art. 81(2) as proposed by the Commission is to clarify that certain **data processing activities** are to be regulated as research activities under Art. 83 and not as healthcare or public activities under Art. 81. Adding requirements to Art. 81(2) concerning the processing activities described therein will lead to confusion and legal uncertainty.

- AMs 334, 335, 336, 337 and 3060 - **health research** is already highly regulated. These amendments add an additional and unnecessary layer of regulation and will result in inconsistent requirements across member states, impeding research and development of important new treatments and contrary to the Regulation's goal of harmonisation.

- AM 3061: The processing of **anonymous data** is not and shouldn't be covered under the Regulation.

Consent: Consent is an important **ethical principle in health research**. In the clinical research context, for example clinical trials, consent is obtained as a matter of good clini-

cal practice. However, a requirement for *consent for processing of health data* for research purposes is impossible in certain observational research studies, for example because a very large sample size is needed to generate a robust result and this would be practically difficult to obtain, or because seeking consent would introduce bias. In situations where consent for processing is not sought, it is particularly important that appropriate safeguards are in place, for example ethics committee approval.

Consequently, EAPM strongly supports AMs 498, 3066, 3076 and 3079. The **option of broad consent** is crucial in the context of collecting and storing data for future research purposes which can only be described in broad terms.

It is important to note that broad consent will not be sufficient to enable some observational studies to continue, and it is vital that the Regulation provides these studies with a clear alternative legal basis to consent.

Definition of Genetic Data: EAPM supports the revised definition of genetic data proposed by AMs 772, 773, 774 and 776. This proposed definition is aligned with international standards, namely the one used in the United Nations International Declaration on Human Genetic Data. Consequently, EAPM opposes AM 775.

Data Breaches: EAPM endorses the introduction of a risk-based approach to breach notification like proposed by AMs 1950, 1953, 1955, 1956, 1959 and 1999.

Data Protection impact assessments: EAPM supports, like suggested by AMs 2018, 2022 and 2023, that a new privacy impact assessment should be required only where a process or project poses substantially new or different privacy risks from what has been analysed in the past.

Codes of Conduct: Approved self-regulation instruments like Codes of Conduct should be encouraged and enable those adhering to such codes to reduce the administrative burdens associated with regulatory compliance. Therefore, EAPM supports AMs 2348 and 2350.

Cross-border transfers of personal data: Cross-border transfers of personal data for research purposes should be permitted subject to the new requirements in Art. 83 concerning such transfers. Multinational research studies require the collection, aggregation and analysis of data from sites around the world. Therefore, we strongly support AMs 2432, 2437, 2438, 2510, 2997, 3075, 3077, 3094 and oppose AM 2497.

Prior authorization: EAPM believes that a request for prior authorisation from the supervisory authority will add burden and delay data processing. Therefore EAPM strongly supports AMs 2094, 2095, 2096, 2097, 2443, 2445 and 2446.

Right of the data subject to information: It is not always possible or proportionate for researchers to provide information to data subjects because of the scale of the study or because data was collected a long time ago, so it is important that there is a 'disproportionate effort' exemption from the right of the data subject to information in Article 14. EAPM strongly supports AMs 1256, 1257, 1263 and 1267 and opposes 1245.

Next Steps: Over the next weeks and months, EAPM will be working with its members to convey these key points at the European and member state level.

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About EAPM

The European Alliance for Personalised Medicine brings together Europe's leading healthcare experts and patient advocates to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics.

It is calling for the European Commission, the European Parliament and EU member states to help improve the regulatory environment so that patients can have early access to personalised medicine, and so that research is boosted.