Comments to the EMA Discussion Paper for Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures

"*The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes*"

- We would suggest particularly considering the processing of data collected from vulnerable populations, patients affected by rare diseases, minors as well as genetic data and data related to samples. In particular, secondary use of personal data is remarkably challenging for research especially in paediatrics since there is a lack of specific provisions covering paediatric peculiarities in the rules introduced by the GDPR, especially in the case of secondary use of data in international research projects and a new overall governance of personal data processing for health research in order to reduce the risk of infringements of fundamental and child' rights it is deemed important to be developed.[1]
- We would suggest replacing "*Paediatric Development Plans*" with "*Paediatric Investigation Plan*" (PIPs) in the *Secondary use of health data* section.
- We encourage you mentioning the multiple database research which is needed especially in the field of rare diseases and in paediatrics in the *Secondary use of health data* section. Combining different databases is often necessary to gather evidence from different countries and provides information on the impact of different public health interventions and strategies on larger numbers of patients and complementary types of information that might be useful for regulatory and policy decision-making, both at Union and national levels.
- In the section *Establishing the legal basis for processing personal data,* reference should be added to the minors reaching the age of legal competence.
- "*The principle of transparency requires that any information and communication relating to the processing of personal data is easily accessible and easy to understand and that clear and plain language is used*". Reference to vulnerable population, illiterate and paediatrics should be made in the *Transparency* section.
- Particular attention should be paid to minors and reference should be added in the text of the *Rights of the "data subject"* section including the best way to inform minors about their rights and how they can exercise their rights. Should this information be included in the assent forms and informative material for children? Should minors directly contact the DPO to exercise their rights? Moreover, reference to the minors that reach the age of legal competence and want to exercise their rights should be made.
- As a conclusive comment, we believe that, in the perspective of fostering research and developing innovative medicines by accessing personal data, further work on acceptable and

[1] A. Altavilla, J. Herveg, V. Giannuzzi, A. Landi, A. Ceci. The Secondary Use of Paediatric Data Under GDPR: Looking for New Safeguards for Research. European Pharmaceutical Law Review. 2019. Volume 3, Issue 4.156 - 164

balanced solutions for everyone, particularly taking into account the peculiarities of specific contexts (rare diseases, paediatric medicines, etc.) is necessary.[2]

This document is prepared on behalf of:

- **TEDDY - European Network of Excellence for Paediatric Clinical Research, Health Data Working Group**

[2] J. Herveg, A. Altavilla. Introducing Key Elements Regarding Access to Personal Data for Scientific Research in the Perspective of Developing Innovative Medicines. May 2020. European Journal of Health Law 27(3):1-18 DOI: 10.1163/15718093-BJA10011