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06/12/2023

AMENDMENTS: 3

Tomislav Sokol, Annalisa Tardino
European Health Data Space

A9-0395/2023

Proposal for a regulation COM(2022)0197 - C9-0167/2022 – 2022/0140(COD)

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6.12.2023

Amendment 1

Patrick Breyer, Pierre Larrouturou, Alexandra Geese, Alice Kuhnke, Anna Cavazzini, Bas Eickhout, Benoît Bîteau, Caroline Roose, Claude Gruffat, Damian Boeselager, Damien Carême, Erik Marquardt, Francisco Guerreiro, François Alfonsi, Gwendoline Delbos - Corfield, Jakop G. Dalunde, Jutta Paulus, Karima Delli, Manuela Ripa, Kim Van Sparrentak, Malte Gallée, Marcel Kolaja, Margrete Auken, Marie Toussaint, Markéta Gregorová, Mikuláš Peksa, Pär Holmgren, Rasmus Andresen, Rosa D'Amato, Sara Matthieu, Sarah Wiener, Ska Keller, Saskia Bricmont, Sergey Lagodinsky, Thomas Waitz, Tineke Strik, Alviina Alameetsä, Clare Daly, Cornelia Ernst, Marisa Matias, Ivan Vilibor Sinčić, Martin Sonneborn, Jarosław Duda, Karen Melchior, Mounir Satouri

Report

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COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)

Proposal for a regulation

Article 3 – paragraph 9 a (new)

Text proposed by the Commission

Amendment

9 a. 9a. Member States shall provide for an accessible and easily understandable mechanism for restricting access pursuant to paragraph 9, whereby prior to the first access for primary use, natural persons shall be asked orally whether they wish to restrict access, and be offered the possibility to, as they prefer, orally, in writing or electronically express their wish to restrict access. Natural persons shall also have the possibility to restrict access at a later stage.

Or. en

Justification

Following the principle of data minimisation there is no need for mandatory registration of health data which cannot be used because of patient opt-outs. Due to the risk of unauthorised access to or unauthorised disclosure of health data that is imminent in the collection and registration of health data in interconnected Electronic Health Records, patients may refrain from seeking treatment if they cannot keep sensitive conditions and therapies off interconnected Electronic Health Records. Member States should therefore be able to give patients a right to

opt-out of the registration of their health data in interconnected Electronic Health Records by all or specific healthcare providers.

6.12.2023

Amendment 2

Patrick Breyer, Pierre Larrouturou, Alexandra Geese, Alice Kuhnke, Anna Cavazzini, Bas Eickhout, Benoît Biteau, Caroline Roose, Claude Gruffat, Damian Boeselager, Damien Carême, Erik Marquardt, Francisco Guerreiro, François Alfonsi, Gwendoline Delbos - Corfield, Jakob G. Dalunde, Jutta Paulus, Karima Delli, Manuela Ripa, Kim Van Sparrentak, Malte Gallée, Marcel Kolaja, Margrete Auken, Marie Toussaint, Markéta Gregorová, Mikuláš Peksa, Pär Holmgren, Rasmus Andresen, Rosa D'Amato, Sara Matthieu, Sarah Wiener, Ska Keller, Saskia Bricmont, Sergey Lagodinsky, Thomas Waitz, Tineke Strik, Alviina Alametsä, Clare Daly, Cornelia Ernst, Marisa Matias, Ivan Vilibor Sinčić, Martin Sonneborn, Jarosław Duda, Karen Melchior, Mounir Satouri

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Proposal for a regulation

Article 33 – paragraph 5

Text proposed by the Commission

Amendment

5. *Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.*

5. Natural persons shall *have the right to opt-out of the processing of their electronic health data for secondary use. Member States shall provide for an accessible and easily understandable opt-out mechanism, whereby prior to the first use of their health data for secondary purposes, natural persons shall be asked orally whether they wish to opt-out and be offered the possibility, as they prefer orally, in writing or electronically to express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes. The exercise of this right to opt-out shall not affect the lawfulness of the processing that took place under Chapter IV before the individual opt-out and shall not place undue administrative burdens*

Justification

Ensuring effective patient control over their health data is key to safeguard trust and acceptance of the European Health Data Space. Depending on the health, literacy, digital literacy and age of a person, written or electronic procedures may be too complicated to understand their right to opt-out of secondary use and to exercise it. To ensure that everybody is given a real choice, every person should be asked at least once orally whether they wish to opt-out before any use of their electronic health data for secondary purposes takes place.

6.12.2023

Amendment 3

Patrick Breyer, Pierre Larrouturou, Alexandra Geese, Alice Kuhnke, Anna Cavazzini, Bas Eickhout, Benoît Biteau, Caroline Roose, Claude Gruffat, Damian Boeselager, Damien Carême, Erik Marquardt, Francisco Guerreiro, François Alfonsi, Gwendoline Delbos-Corfield, Jakob G. Dalunde, Jutta Paulus, Karima Delli, Manuela Ripa, Kim Van Sparrentak, Malte Gallée, Marcel Kolaja, Margrete Auken, Marie Toussaint, Markéta Gregorová, Mikuláš Peksa, Pär Holmgren, Rasmus Andresen, Rosa D'Amato, Sara Matthieu, Sarah Wiener, Ska Keller, Saskia Bricmont, Sergey Lagodinsky, Thomas Waitz, Tineke Strik, Alviina Alametsä, Clare Daly, Cornelia Ernst, Marisa Matias, Ivan Vilibor Sinčić, Martin Sonneborn, Jarosław Duda, Karen Melchior, Mounir Satouri, Tilly Metz, Lydie Massard, David Cormand

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Proposal for a regulation

Article 34 – paragraph 1 – point e

Text proposed by the Commission

Amendment

(e) scientific research related to health or care sectors;

(e) scientific research related to health or care sectors, ***contributing to public health or health technology assessment, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, with the aim to benefit the end-users, such as patients, health professionals and health administrators, and where anonymised***

data is processed: (i) development and innovation activities for products or services; (ii) training, testing and evaluating of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications; (iii) university and post-university teaching activities related to scientific research;

Or. en