

EFA's response to the public consultation on a European Strategy for Data (Directorate General for Communications Networks, Content and Technology)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of the 200 million people living with allergy, asthma and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 43 national associations from 25 countries and channel their knowledge and demands to the European institutions. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care and a safe environment.

EFA welcomes the communication of the European Commission on a European Data Strategy as a timely proposal that fits well within the current digital transformation. Of great interest for our patient community is the announced intention to create common data space in the areas of health and sector policies within the Green Deal.

Patients are undoubtedly benefitted by the digital revolution in the area of health, both at individual use and at macro levels. eHealth and mHealth offer a great potential for patient empowerment and the modernization of health systems respectively, which can facilitate patient-centricity in health and personalised medicine in care.

In the case of chronic respiratory conditions with strong interlinkages with the external environment, such as asthma and chronic obstructive pulmonary disease (COPD), digital tools can transform disease and self-management patterns, from diagnosis to therapy to morbidity. Such tools and applications are typically fed by patient data, and are only possible through sharing these data.

For example, **misdiagnosis** remains a major clinical concern allergy, asthma and COPD. According to the EFA Active Patients Access report findings, 16% of asthma patients get a wrong first diagnosis, while this percentage is also holds true for COPD patients¹. New and digitalized data can support researchers better identify **phenotypes** and underlying disease mechanisms, classifying bulk diseases such as asthma and therefore leading to more specific treatments and quality of life.

Besides, a digital health system that monitors the disease over time and collects data (home monitoring), assist patients **assess** their disease progress **empowering** them to take with their healthcare professionals optimal care decisions. Furthermore, digital health can transform **adherence**, improving treatment outcomes. In line with the recommendation contained in the EFA HEY YA! report, mHealth can be a perfect way to combat forgetfulness, which is one of the most common, unintentional causes of non-adherence².

The benefits of digitalisation, data gathering and analysis outweigh its drawbacks. This is why patients and their representatives are mostly willing to share their data for research purposes, the

¹ EFA Active Asthma and COPD Patients Access Care Report, 2019

https://www.efanet.org/images/ShowLeadership/Report-Showleadership_FINAL.pdf

² EFA Health Literacy, Young Patients with Asthma and Adherence to Treatment: EFA Report and European Recommendations, 2016

https://www.efanet.org/images/2016/EFA_Report_HEY_YA_Health_Literacy_Young_Patients_with_Asthma_and_Adherence_to_Treatment_2016_April.pdf

advancement of cutting-edge technology, and boosting digitally-enabled, person-centered care models. Yet, **health data are the most sensitive facts of an individual**, and therefore require strong regulatory framework that protect how data is created, owned, stored, and exploited, especially if these data will then inform healthcare decision-taking. As nowadays the flow of big data is vast, having generated a full-fledged new industry, issues pertaining to privacy and data protection need to be urgently addressed.

1. A common European health data space

As Members of the European Patients Forum (EPF), EFA fully endorses and agrees with the EPF response to this consultation. EFA welcomes the recognition of the need for a sector-specific approach on health, considering the strategic nature of the health sector and its specific challenges and risks. At EFA we fully share the views of the European Patients Forum that a common European health data space should be founded on **robust governance** that ensures **meaningful patient involvement** at all stages. Given the sensitivity of health data, **a framework of trust and ethical standards** around how data are being used and processed is of outmost importance³.

For this to be possible, the future common European health data space should successfully address the following issues:

- **Ownership and consent** – Patients should be the ones to own and decide to whom they share their data and under what conditions. Consent should be clear and uniform, allowing for withdrawal of data at any point
- **Data collection**– Patients should know the means through which their data are collected, but also be able to share only the data that are absolutely needed
- **Access** - Patients should always have access to their data, as well as the right to modify and withdraw them. The General Data Protection Regulation confirms that the right to access your own personal data is part of your fundamental right to data protection, and explicitly mentions the right to access your medical record
- **Portability/Interoperability** – Data should be developed in such a format that renders them portable and interoperable within and across countries, and among different electronic applications
- **Use** – It should be clear to patients how their data are used by public or private actors, as well by healthcare professionals to drive decisions on care
- **Data protection and privacy** – Health data are personal data and are to be protected, according to the Charter of Fundamental Rights of the European Union⁴. Besides, especially for research purposes where exemption to consent exists, safeguards should be in place such as the anonymization of data.

Considering the long-term treatment requirements of chronic conditions such as allergy, asthma and COPD, EFA supports every initiative that reinforces the cross-border exchange of data in the context of existing structures such as the **Electronic Health Records and ePrescriptions**, provided that they are in compliance with General Data Protection Regulation.

³ European Patients Forum Briefing Paper, *Big data and artificial intelligence*, April 2020
<https://www.eu-patient.eu/globalassets/policy/epf---big-data-and-artificial-intelligence---eu-policy-briefing-for-patient-organisations-april-2020.pdf>

⁴ Charter of Fundamental Rights of the European Union, 2012 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN>

In addition, **education and digital literacy** need considerable attention, as they represent key elements of empowerment. Of particular relevance here are diseases such as COPD, which typically affects the elderly. Through targeted actions, all age groups should be offered the possibility to join the digital culture that today emerges in our societies. This can be achieved by bringing on board healthcare professionals to ensure accurate information is given to patients, especially when living with a chronic disease.

Accordingly, EFA is advocating for an earmarked space for **citizen science** in the area of health: the development and integration of patient-driven, real-world evidence data that serve self-management and meaningful patient-reported outcomes.

2. A Common European Green Deal data space

At EFA we consider it crucial to explore the ways data policy can help materialise the landmark EU environmental goals as reflected in the European Green Deal, including climate-neutrality by 2050, as well as the ambition for a zero air pollution, due to be unfolded in 2021. We therefore welcome the intention of the Commission to put forward initiatives that are cross-cutting and synergistic by nature, such as the GreenData4All.

Air pollution remains a major concern for Europeans, as a Eurobarometer survey report showed in 2019⁵. It is associated with about 400,000 premature deaths annually in Europe⁶. Moreover, a large majority of the European population, including vulnerable groups such as patients with asthma, allergy and COPD, continue living in polluted environments –mostly urban- which are harmful for their respiratory health. According to the EFA Active Patients Access report, 7 out of 10 asthma and COPD patients feel that the authorities are not doing enough to protect them from outdoor pollutants⁷.

In light of these risks, digital technologies applied to data can simplify the collection of information on areas that need continuous measurement, including air quality and exposure to chemicals. Naturally, the new knowledge arising from data collection on pollutants should be communicated and of easy **to access**.

Finally, EFA would like to draw the Commission's attention to **pollen emissions**, intrinsically linked with the onset of respiratory allergy. Despite pollens being from natural sources, they are very much affected by human industrial processes. As patients, we are affected by the pollen issued and increased due to man-made activities such as mass culture or due to the **effect climate change has on flora**. Current research shows that independently of the species planted for food, climate change is contributing to extended seasonal duration and increased pollen load for multiple aeroallergenic pollen, heavily impacting human health⁸⁹.

EFA holds that a comprehensive Green Deal data space should also include the collection of data on natural organic pollutants, thus becoming the driving force of a **real-time monitoring of pollen**. Such

⁵ Special Eurobarometer 497 report, *Attitudes of Europeans towards Air Quality*, 2019
<https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/survey/getsurveydetail/instruments/spacial/surveyky/2239>

⁶ European Environment Agency, *Air Quality in Europe*, 2019 <https://www.eea.europa.eu/publications/air-quality-in-europe-2019>

⁷ EFA Active Asthma and COPD Patients Access Care Report, 2019
https://www.efanet.org/images/ShowLeadership/Report-ShowLeadership_FINAL.pdf

⁸ Ziska L. et al., *Temperature-related changes in airborne allergenic pollen abundance and seasonality across the northern hemisphere: a retrospective data analysis*, March 2019
[https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196\(19\)30015-4/fulltext](https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(19)30015-4/fulltext)

⁹ Damialis A., Traindl-Hoffmann C., Treundler R., *Climate Change and Pollen Allergies*, June 2019,
https://link.springer.com/chapter/10.1007/978-3-030-02318-8_3

a framework remains as urgent as ever, as it would ensure the timely dissemination of and access to information to citizens with pollen allergies.