Tackling the regulatory pain points of digital health startups in the EU

1. **Access to a European single market in healthcare**

More harmonisation of regulatory requirements at the EU level can help reduce market fragmentation, costs and increase the overall healthcare quality. **Making the regulatory process more transparent and easier to navigate** and establishing a pan-European interoperable regulatory system can maximise patient-centred outcomes. A guideline on such regulations could be one way of improving this.

Regulatory sandboxes can be a powerful tool where conventional methods are too costly or prove ineffective. A European framework on regulatory sandboxes could provide guidance and legal certainty.

Although startups have a demonstrated value in improving patients' quality of life, they struggle to prove the added economic value of their products. Overcoming the silo mentality by providing avenues for **more collaboration and co-creation** between corporations, healthcare institutions, policymakers, startups, insurers and clusters from the design to the marketing stage will not only improve health outcomes for patients but also financially benefit national healthcare systems.

The new medical device regulation is coming into effect in May 2020 and only a limited number of notified bodies are ready to operate to certify devices. The new regulation is very resource-demanding from a startup perspective. There is room for a more differentiated regulatory approach that better captures the requirements.

Taking the example of Germany's new law that allows the reimbursement of a range of digital health apps, **harmonising reimbursement systems at the EU level** is beneficial for healthcare providers and patients alike, encouraging the uptake of digitalisation in health.

2. **A common European data space in healthcare**

Improving access to public data and fostering measures to encourage private data sharing is vital. The legislation on the secondary use of health and social data that came into effect in Finland in May 2019 is a great example of facilitating access to a larger pool of data for better research and innovation, while respecting data privacy. This also shows the necessity for best practice sharing and cross-border cooperation among Member States.

The issue of trust also needs to be addressed by a wide range of stakeholders, including policymakers. Safety in data sharing should be a priority and patients should have more governance over their data.

Widespread use of electronic health records (EHR) for the exchange and use of health data in the EU can facilitate cross-border interoperability and reduce the cost of healthcare significantly. This will allow better and faster innovation, while respecting citizen privacy.

Paving the way for scientific research at the EU level through a common data space in health can add to the EU's initiatives to build a data economy. This can be achieved through providing **more legal certainty on data sharing**.

3. **AI in health**

While ethical guidelines to inform AI development are necessary and useful at the EU level, **regulation should be straightforward and flexible**. This will enable more innovation and investment in AI.

Data quality is vital for harnessing the full potential of AI. Improving access to and encouraging free movement of data will add to better healthcare.

More funding can make the EU an AI champion. Initiatives such as the Commission's plan to support the development of a common database of health images (anonymised and voluntary) in 2020 to improve diagnosis and treatment of common forms of cancer, and similar initiatives that also cover other areas of healthcare, can boost the uptake of AI in Europe.