

Note of an audio meeting between Commissioner Breton and eHealth Stakeholders, 6 April 2020

eHealth Stakeholders: (1) [redacted] COCIR; (2) [redacted]
[redacted] Siemens Healthineers; (3) [redacted]
[redacted] SANOFI; (4) [redacted]
[redacted] Bytetflies; 5) [redacted] Kry.care; (6) [redacted]
[redacted] Philips.

Key points raised by the eHealth stakeholders

COCIR [redacted] **GDPR guidance** for the use of data in the context of COVID 19 is critical to go fast and to avoid fragmentation. An EU approach to supporting **telemedicine and tele-monitoring** is urgently needed, such as in relation to reimbursement policy to support their uptake by health professionals.

Deployment of existing innovation and initiatives (telemedicine, roll out of e-prescriptions) in health digital transformation is too slow and needs to speed up. Urgent need to speed up the European Health Data Space, particularly the interoperability of health data, and deployment of e-prescription, patient summary and better use of EHRs. Existing interoperability profiles should be more widely used, such as in public procurement tenders for health care ICT.

Siemens Healthineers [redacted] their priority now is to secure workflows (supply chains and R&D processes), to support healthcare systems to meet the challenges of COVID19 and management of other conditions. With specific regard to COVID19, company is ramping up their scanning facilities, such as computer tomography, to support diagnoses alongside X-ray and ultrasound; and developing a molecular based test.

Digital health transformation is more important than ever, and has a valuable role during pandemic to protect clinical staff and patients. They call for (1) Clarity on the GDPR basis essential for the fast development of algorithms, alongside easier access to data; (2) need to assure continued free trade as critical parts of the data value chain (e.g. as relates to critical supplies) comes from outside the EU; (3) Looking forward, speeding up the European Health Data Space will be important.

Sanofi [redacted] informed that they are developing two vaccines against COVID-19 with the support of the US Government, with one based on recombinant DNA technology. Time-frame for producing the vaccine is 18 months. Thought needs to be given now as to how to ramp up production capacity, to make the volume of vaccine that will be required. The EU can support an increase in production capacity, such as through involvement in purchase of raw materials. Vaccine stocks will also need to cover a second wave in the autumn that, unlike the first one, will overlap with the flu season, complicating response.

Getting this far so fast with vaccine development has been possible through use of electronic health records. One prospective, randomised clinical trials, coordinated by US based Kaiser Permanente is based on the EHRs of 1.6 million people. The second, led by a Finnish group, has randomised the EHRs of 68,000 people. Such clinical trials using EHRs (in-silico methods) allows for the complete reinvention of the clinical trial model. If the EU can move faster to make EHRs available, it will become a world leader in drug and vaccine development. This would promote employment, and

reduce price of medicines. It needs interoperability of EU health data systems, common technical specification, common approaches to IT systems and data protection.

Byteflies [redacted] : emphasised that wearable health devices can enable remote monitoring which supports pandemic response by keeping patients away from hospitals, particularly the elderly. The current pandemic appears to be shifting the minds of healthcare decision-makers towards these devices.

Three important aspects for the EU: 1) the speed of the market to implement innovation everywhere, 2) the need to assure cash flow for small digital innovation companies at this time (given that they continue to invest in hiring people & take on other risks, and 3) the speed of certification of Apps. Even simple innovations take 6 months to a year, whereas the FDA can certify in three days. Strong political support is needed, with dedicated investments and a timeframe to achieve.

Krys.care [redacted] : Use of telemedicine is expanding. Krys is bringing on board many new clinicians at great speed: some are retired so the process unlocks unused talent. They have also created Kry Care.connect as a free and secure service on offer to all MS's now, and which can support the COVID19 response.

A challenge to widespread uptake comes from the different levels of maturity in the MS markets: some markets discriminate between digital and physical consultations when it comes to reimbursement.

Philips [redacted] : Digitisation is happening at a faster speed than before the COVID 19 crises. We are seeing greater take up of activities, such as the use of predictive analytics in ICU for patient care optimisation and system efficiency. Two examples: (1) patients are being transferred between hospitals nationally and internationally, due to lack of local ICU capacity. In the Netherlands, there is a COVID-19 portal to support the exchange of health data for these patients. Setting this up quickly was possible thanks to a strong central role in the design of the model, central coordination, and the mandatory requirement that all actors use the model, (2) Hospital ICUs are increasing using digital remote monitoring tools. For example, using AI based predictive analytics can identify signs of patients' deterioration earlier than can a human. This is safer for the health personnel and patients.

There is a clear role for governments and the EU to facilitate data exchange. Following actions are proposed: (1) An EU data-sharing portal could be set up in 4 weeks if the EU supported it, with the right level of commitment; (2) Yes accelerate the Health Data space, but not only within EU, include also other countries, such as China. This will allow COVID-19 algorithms to be developed faster, using more representative data, using also data from countries further ahead in the pandemic; (3) designate healthcare providers as critical infrastructure. This will accelerate our response to the next waves of pandemic as well to the constantly high burden of chronic conditions.