Call with European eHealth companies/sector organisations
6 April 2020

Context and objectives:

This crisis is a stark reminder that the digital transformation of the health and care sector has to accelerate.

This meeting will aim at examining systemic issues in the digitisation of healthcare and zooming in on specific, innovative e-health solutions which may be become part of our life after the crisis.

We talk a lot about AI, high performance computing, big data and how technology can support the health and care sector, and improve the quality of care for European citizens. What the crisis has shown is that these discussions, this work we have done has not yet been translated into clinical practice, or into public health preparedness. When a rapid response to COVID-19 was needed, technological solutions to support the response were not readily available, as the supply chains to deliver them.

Our preparedness and response at national and European level was not rapid enough and not enough coordinated. Differences across Member States persist in the digital transformation of the health and care sector; this is also reflected in the potential to apply these technologies to the response to this health crisis.

The e-health sector is also one with the potential to innovate quickly and hence new solutions will surely be part of the exit strategy. After the crisis, there may be increased focus on specific e-health solutions, for example in terms of telemedicine.

This meeting with different voices within the sector will allow you to highlight:

- **The need to take a quantum leap into the future**. Digital solutions to support the crisis response are urgently needed. A bold approach and a collective, cross-sectoral effort is warranted if we are to deliver effective solutions in time to fight this crisis.

- **Digital transformation is key.** In times where healthcare systems are understaffed and under an unprecedented pressure, digital solutions are key in delivering faster and more effective care where it is more needed. AI and technology can offer support to diagnostics, prognostic, clinical workflows in the hospitals – but also about to supply chains, helping prioritising and matching needs and solutions.

- It is necessary to insist with authorities about **interoperability.** Improved care is delivered and research advances when knowledge is shared; to do so, it is essential that all parties involved speak the same language and can understand each other. The European Commission has adopted a Recommendation on a European Electronic Health Record exchange format; it is crucial that it is evenly implemented across European countries, to unlock the flow of health data across borders.

- It is crucial that health authorities are engaged in the run up to the **European Health Data Space**. The amount of data already available on COVID-19, if pooled and used, could make a difference in our understanding of the disease and of the optimal treatment for each patient.

- You will be able to hear from companies with which **solutions** they are supporting the management of the crisis and whether there is a role for the Commission to play in that. You can discuss how to prepare for the new normal & understand what **opportunities it could bring for this sector.**

Running order:

- Initial remarks by Commissioner Thierry Breton

- Viewpoint from the health ICT sector:
  COCIR, (the European Trade Association representing imaging, radiology and health ICT);
  is also on the regular Friday calls with you and Commissioner Kyriakides.

- Viewpoint of a leading technology company:

  Siemens Healthineers

- Viewpoint of a multinational pharmaceutical company active in the eHealth sphere:
  SANOFI (it partners with Google on emerging data technologies in medicines and heathcare)
  SANOFI is also on the regular Friday calls with you and Commissioner Kyriakides, but represented by a different person.

- Viewpoint of a startup in wearable health devices:
  Byteflies (Belgian health tech startup)

- Viewpoint of a company providing telemedicine services:
  Kry.care - also known as LIVI in France (a digital healthcare provider operating in five European countries, with a platform enabling healthcare professionals to see and treat their patients remotely)

- Looking ahead: COVID-19's impact on the on-going digital transformation of health and care:

  Philips.

- Reactions, discussions and questions

- Wrap up and next steps by Thierry Breton

- **I am aware that healthcare systems are heavily impacted by the coronavirus,** and capacities are increasingly stretched. As the continent recovers, there will be renewed urgency to consider what innovations can support greater resilience in these systems.

- I am convinced that the only solution is to take a **quantum leap into the future**. Digital solutions to support the crisis response are urgently needed.

- A bold approach and a collective, cross-sectoral effort is warranted if we are to deliver effective solutions in time to fight this crisis.

- To achieve this, **digital transformation is key.**

- In times where healthcare systems are understaffed and under an unprecedented pressure, digital solutions are key in delivering faster and more effective care where it is more needed. AI and technology can offer support to diagnostics, prognostic, clinical workflows in the hospitals – but also about to supply chains, helping prioritising and matching needs and solutions.

- We need to address the current situation **but also start to assess what will be needed for "the day after".** AI and

technology can offer support to diagnostics, prognostic, clinical workflows in the hospitals – but also about to supply chains, helping prioritising and matching needs and solutions. These solutions are a priority in the current times of crisis, but will also be a forerunner, a model for eHealth solutions for the future.

- The eHealth sector is one of the areas in which we need to strengthen and to see greater integration of digital tools, for example, into health and care systems in the EU.

- **However, differences across Member States persist in the digital transformation of the health and care sector**; this is also reflected in the potential to apply these technologies to the response to this health crisis. It is necessary to insist with authorities about **interoperability.** The European Commission has adopted a Recommendation on a **European Electronic Health Record exchange format; it** is crucial that it is evenly implemented across European countries, to unlock the flow of health data across borders.

- This will need **an actively engaged ecosystem** comprising companies (large to start-ups), secure access to the necessary health data and high performance computing services, as well as facilities for testing and experimentation. This is in addition

to a framework for the governance of artificial intelligence for which the health and care sector is a key user.

- It is also crucial that health authorities are engaged in the run up to the **European Health Data Space.** This crisis is a stark reminder that the digital transformation of the health and care sector has to accelerate. **The amount of data already available on COVID-19,** if pooled and used, could make a difference in our understanding of the disease and of the optimal treatment for each patient.

- These measures are being addressed through the recent Digital Package that was published in February 2020.

- We have a number of **direct COVID related initiatives**, with some of you involved, that are engaged in this, including:
  - o **modelling the COVID-19 outbreak**, to support mapping current initiatives in epidemiologic modelling with the aim of identifying synergies among different initiatives including in the digital sectors (HPC, AI).
  - o **Use mobility data** (traffic/location data) **from European mobile operators** in an aggregated, anonymised form for necessary data analytics.
  - o **Creating a space dedicated to Covid-19 on the European Data Portal**

- o the **Exscalate4CoV research initiative** to find effective molecules to tackle the pandemic using **high performance computing**
- o Working with MS to share best practice on **tracing Apps**
- o **Collating digital tools** through both our financed mHealth Hub project (managed by the WHO/ITU) and our eHealth Hub

Now I am turning to you as I am curious to hear from you

- What is the current impact of the ground, for your company /organisation, as a result of the current crises?

- What can you offer to make sure that the data that we need in crises time is readily available and available also to Governments in the vital interests?

- The Commission is aware that companies are supporting the COVID-19 crises, what kinds of activity are you doing, and is there a way that the Commission can further facilitate it?

I am also interested to discuss

- How does the sector see the impact on the on-going work to digital transform health and care?

- What challenges and opportunities do you see, beyond the end of the pandemic?

<u>Possible elements for the conclusion</u>

- The digital transformation and the role of data in the crises is fundamental

- We need to have the ability to **share health data** in the vital interest when we need to.

- Our **actions on health data,** such as the work to develop the interoperability of health data put in place by the Commission Recommendation adopted last year on a European Electronic Health Record Exchange format remains critical

- I see **health data as a key asset for EU data sovereignty.** You will be aware of our plans for a health data space and an open Industrial Forum (as part of the recent Industrial strategy). It is critical eHealth industry is represented in this Forum.

- **We need to continue and strengthen this engagement.**

<u>Defensives (based on questions received so far from the industry)</u>

Q. We are supporting the COVID-19 crises in many ways, and seek to keep the Commission informed of our actions. What is the most appropriate way to share this information?

A. The best way is to publish what you are doing in an open data approach. The Commission would be an imperfect funnel for information that is needed across the EU, often in health care providers or health competent authorities. Please do continue to share your information with us because we value the engagement and are interested and will react where we see an EU dimension. However, we urge you to keep doing –as you are doing – publishing your activities on your website, and through your social media channels.

Biographies

COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007.COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Siemens Healthineers

Siemens Healthineers is a leading medical technology company with over 120 years of experience and 18,500 patents globally. With over 50,000 employees in more than 70 countries, we'll continue to innovate and shape the future of healthcare.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare.

An estimated five million patients worldwide everyday benefit from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine as well as digital health and enterprise services.

SANOFI

Sanofi S.A. is a French multinational pharmaceutical company headquartered in Paris, France,

Sanofi engages in the research and development - invested €5,894 million invested in R&D in 2018 - , manufacturing and marketing of pharmaceutical drugs principally in the prescription market, but the firm also develops over-the-counter medication. The company covers seven major therapeutic areas: cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines (it is the world's largest producer of the latter through its subsidiary Sanofi Pasteur).

Sanofi has a 'digital laboratory' just outside Paris that will be dedicated to advancing its eHealth work in France.

As part of its efforts to develop eHealth solutions the firm aims to harness areas such as connected objects, big data, block chain, serious games and artificial intelligence.

Sanofi and Google is working on a new virtual Innovation Lab with the ambition to radically transform how future medicines and health services are delivered by tapping into the power of emerging data technologies

Byteflies

Byteflies (°2015) is a Belgian health tech startup that offers B2B-services to enable lean wearable health development. At Byteflies we envision a future where healthcare is truly personalized, predictive, preventive, and participatory. Wearable technologies that enable 24/7 acquisition of accurate and synchronized vital signs and clinically-validated digital biomarkers are a crucial facilitator of this transition. Byteflies creates a platform for rapid development of application-specific wearables as a critical tool to enable precision medicine for various medical conditions.

Kry (also known as LIVI in France)

Swedish KRY (known as LIVI in the UK and France) operates both digitally and on the ground in five European markets (France, Germany, Norway, Sweden, UK).

It allows people see a doctor over video on their smartphone. Kry is not "just a platform" connecting doctors and patients, it is a healthcare provider. It employs its own clinicians and in certain countries has its own health centres. A doctor's appointment at KRY is therefore equivalent to a regular doctor's appt provided that the condition can be diagnosed without physical examination.

With 500 staff members and close to 2000 clinicians within its own service, KRY can be considered the largest digital healthcare provider in Europe.

Royal Philips

Royal Philips is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. Philips leverages advanced technology and deep clinical and consumer insights to deliver integrated solutions. Headquartered in the Netherlands, the company is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care. Philips generated 2019 sales of EUR 19.5 billion and employs approximately 80,000 employees with sales and services in more than 100 countries.

Background information on sector specificities

Prior to the pandemic, the global market for ICT solutions for healthcare monitoring in private homes is expected to grow from nearly EUR €10.7 billion in 2016 to roughly EUR €31.5 billion by 2021.

McKinsey Global Institute, 2013 – estimates the potential **economic impact of the Internet of Things across healthcare applications** to be USD 1.1 trillion to USD 2.5 trillion per year by 2025.

The **market for mobile health** has been growing steadily over the last years, and continues to do so. In 2017, there were 325,000 health apps (health & fitness and medical apps) available on all major app stores. Since the year before, 78,000 new health apps have been added to major app stores

A tremendous growth is expected especially for the h**ealth data and data analytics market** in the next 5-6 years. Some analysts have predicted that the global health data market will increase from around $14 billion in 2019 to a size of between $50-60 billion in 2025 (Statista 2019). The main growth drivers are believed to be the increasing adoption of healthcare analytics solutions and services by healthcare providers to provide better quality care and lower healthcare costs.

However, AI also brings new challenges to the existing ethical, regulatory and liability rules. While the new EU legal framework on medical devices brings forward up-to-date rules and a safer environment for digital technologies that bear a medical purpose, not all digital technologies fall within this framework and the regulation of digital health services and solutions remains uneven across Member States.

Regarding particular response to the COVID-19 crises, the sector has a role to play in supporting the manufacturing effort for urgent, medical equipment and has been supporting both through traditional production and digital techniques such as 3D printing. In addition, there has been some new and rapid innovation linked to COVID-19 treatment such as new algorithms for the use of lung imaging for COVID-19 patients.

However, on the other hand, the sector has suffered substantial negative impact as the factor represented above represent only a tiny volume of their product lines. These impacts include: staff issues (illness, difficulty in travelling to work/connecting); loss of investment; and supply line difficulties (including transport delays at MS borders).

Key EU policy actions relevant for the sector:

A) In response to the COVID-19 situation

Horizontal measures (as for other sectors include)

- To enable EU State to support companies (subsidies, loans, guarantees, etc.), in particular SMEs, the Commission launched the State aid Framework Flexibility. FR,

ES, DE, LU, DK, UK already notified schemes, many of them supporting the most vulnerable ones (SMEs, etc.).

- To bring immediate relief to hard-hit SMEs, EUR 1 billion will be redirected from the EU budget as a guarantee to the European Investment Fund to incentivise banks to provide liquidity to SMEs and midcaps. This will help 100,000 European SMEs and small mid-caps.

- The Commission also proposed a EUR 37 billion Corona Response Investment Initiative (CRII), notably to provide liquidity to corporates (covering e.g. working capital in SMEs).

- To alleviate the impact of the epidemic on jobs, the Commission accelerates the preparation of the legislative proposal for a European Unemployment Reinsurance Scheme (Communication on coordinated economic response to COVID 19) aiming at supporting MS policies that preserve jobs and skills.

- The European Globalisation Adjustment Fund could also be mobilised to support dismissed workers and those self-employed under the conditions of the current and future Regulation. Up to €179 million is available in 2020.

- Other measures recommended by the Commission include tax holidays, ease of pay-outs, access to cheap credit.

- The EIB will also mobilise up to EUR 40 billion. Amongst them, EUR 10 billion will be dedicated liquidity lines to banks to ensure working capital support for SMEs and mid-caps.

- The ECB announced a €750 billion Pandemic Emergency Purchase Programme (PEPP) and the expansion of the range of eligible assets under the corporate sector purchase programme (all commercial papers of sufficient credit quality are now eligible for purchase under CSPP).

B) **General EU policy actions**

- The Commission Communication on the **Transformation of Health and Care in the Digital Single Market** (COM2018(233) with the three objectives to (1) give citizens better access to their health data anywhere in the EU, (2) use digital tools for citizen empowerment and person centred care, (3) connect and share health data for research, faster diagnosis and improved health outcomes.

- Recommendation on a European Electronic Health Record Exchange Format, (COM2019(800))

- The Commission seeks to leverage EU financing opportunities and data to support the digital transformation of healthcare, ensuring adequate data protection, safety and security, such as the Active and Assisted Living Programme, and European Innovation Partnership both funded by H2020.

- Creation of a European Health Data Space (mission letter of Commissioner Kyriakides, September 2019)

- European [Data strategy](#) & the White Paper on Artificial Intelligence (Digital Package, February 2020)

- Industrial policy: Report by the Strategic Forum for Important Projects of Common European Interest (5/11/2019) made recommendations to support Europe's leadership in six strategic value chains, including to support the European Health Data Space; create an EU Investment Platform for "Smart Health" to support new products and services; stimulate demand and uptake of Smart Health products and services & create a new European Smart Health Innovation Hub to assess and promote Smart Health solutions.

Expectations and positions of stakeholders:

- Many are actively seeking for ways to support the response to the pandemic, and actively sharing this with different parts of the Commission. They may appreciate some guidance as to the best way to communicate this information.

- Aware that the COVID-19 crises brings opportunities for their sector, and hope that support to overcome the various obstacles to the innovation in, and integration of, digital tools into EU health and care systems will increase in the aftermath. (These obstacles include lack of access to health data, regulatory frameworks in the health sector for e.g. medical devices, health technology assessments particularly for digital products involving AI, and also organisational aspects such as incentives.)