COCIR Input to the Roadmap on the Pharmaceutical Strategy[1]

COCIR welcomes the opportunity to provide feedback to the roadmap on the pharmaceutical strategy.

As reference is being made to medical and digital technologies COCIR is happy to share some inputs linked to those sectors covered by our members.

There are 2 elements of the challenges listed in the current roadmap that are linked besides pharmaceuticals to medical and digital technologies:

In challenge 4, the Commission identifies that **innovation efforts are not always aligned to public health and health systems' needs.** Industry (COCIR, EFPIA, MedTech Europe, EuropaBio, VaccinesEurope) has already taken action, by engaging in discussions with the European Commission on a possible European Partnership for Health Innovation[2] under Horizon Europe. The Partnership aims to enable the integration of cross-sectoral technologies, know-how, products, services and workflows for people-centred health care. Its ambition is to support the delivery of timely and well-informed prevention, diagnosis, and treatment. The partnership aims to keep EU citizens in good health, decrease disease burden for patients, care givers and health care professionals. Its governance will be set up in such a way to ensure that any R&D&I funded will respond to the needs of healthcare systems and citizens.

Our recommendation: The pharmaceutical strategy should recommend that appropriate funding is allocated under Horizon Europe to support the ambitions of the future partnership.

In addition, public authorities are increasingly struggling to remain sustainable. Thus, there is an urgent need to move towards **integrated care models**. Shifting towards value-based healthcare will, therefore, reduce waste, increase access to care and improve patient outcomes.

Our recommendation: The new strategy on pharmaceuticals should consider that state-of-the-art ICT-embedding medical solutions can and do provide crucial support to patients and their families, healthcare professionals, policymakers and society. They showcase the transformative value of care throughout the continuum, from prevention and early diagnosis to treatment and home care.

Regarding challenge 6, **Technological and scientific developments may challenge the regulatory framework and consequently lead to unintended barriers to needs-driven innovation**: Health and medical software, including software based on Artificial Intelligence, create many opportunities to support the more efficient development and effective use of medicines. We certainly support increased communication between the European Medicines Agency and medical device regulators, especially for combination products. That also means strengthening the understanding of medical software regulation among pharmaceutical regulators. The new Medical Device Regulation already offers an effective framework for placing safe and performing software, including software-based devices, on the market.

Our recommendation: The strategy on pharmaceuticals should also consider that confusion is avoided, by going beyond the existing legislation. For example, COCIR has been concerned by the

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[1] *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines*

[2] *https://www.EUhealthPPP.org*

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discussions on the EMA's draft guidance on drug-device combinations[3] which expands the understanding of these combinations beyond the current established definition.

In addition, and while looking at the specific holistic objectives COCIR believes the following actions should be tackled:

1. **Ensuring greater access to care**
   COCIR agrees that innovative and promising therapies are not reaching patients possibly due to market failures and national reimbursement policies, as for instance witnessed in cancer care. Reimbursement systems have not been adjusted to reimburse innovative radiotherapy technologies or digital health solutions, nor have there been structural investments to modernise existing infrastructure [4]. This results in unequitable access to care, with EU citizens having differing options for care and outcomes depending on their location.

2. **Enabling innovation including for unmet medical needs including benefits of digital technologies**
   As explained while looking at challenge 4, COCIR agrees that more efforts should go towards innovation, reason why we have actively engaged and are working on the possible establishment of a new European Public Private Partnership on Health.
   The current pandemic has proven the need of having, also in the future, an operational partnership in health innovation as an efficient instrument for swiftly mobilizing and coordinating of public and private efforts.
   Furthermore, the development and deployment of digital health solutions has proven to be effective to structurally support a more patient-centred and personalised care.

COCIR noted that the European Commission recently opened a public consultation on the Pharmaceutical Strategy that will close on 15 September. COCIR will be happy to provide further input through this process.

In the meantime, COCIR calls upon the European Commission to:

- **Promote** genuine collaborative R&D for healthcare through Horizon Europe, for instance under the envisioned Innovative Health Initiative

- **Review and develop** incentives for innovation, remove barriers for market access and ensure a more harmonised approach across Member States

- **Support** the uptake of innovative technology through transparent tendering and procurement processes

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[3] *https://www.ema.europa.eu/en/quality-requirements-drug-device-combinations*
[4] *COCIR call for action: Ensuring cancer treatment in times of COVID-19*

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