Biomedical Alliance in Europe

06 July 2020

BioMed Alliance feedback to the consultation on the Roadmap for the new Pharmaceutical Strategy for Europe

The Biomedical Alliance in Europe (BioMed Alliance) welcomes the new Pharmaceutical Strategy for Europe and the European Commission's intention to create a holistic, patient-centred, forward-looking Strategy. We believe the new strategy could play a key role in ensuring EU initiatives complement each other and help to further strengthen our much-valued European healthcare system.

Clinicians and researchers are active in the forefront of scientific discoveries, in carrying out academic clinical trials and in ensuring optimal treatments for patients. Multi-sector collaboration is needed to ensure that European health research discoveries are aligned to public health and health system needs. The overall strategy should create opportunities to bridge across sectors and to see what gaps there are in the health research ecosystem and how these could be addressed. Therefore, researchers and clinicians' involvement is essential in the lifecycle of pharmaceutical products.

The roadmap presents key elements and we would like to draw your attention to the following points:

Research should play a key role in accelerating scientific developments to enhance access to innovative medicines.

Health research in Europe requires investment and prioritisation in order to make substantial leaps in advancing the health of European citizens and transform health systems. European health research is often scattered and operates in silos. The EU's initiatives have been a step in the right direction, however there are still missing links that should be considered such as:

- A need for long-term strategic planning to strengthen biomedical and clinical research in Europe accompanied by a visionary leadership for health and health research in Europe.
- All stages in biomedical research from basic research to translation and clinical practice are interlinked, therefore all stages should receive necessary funding.
- Skills development and continuing medical education of doctors are essential in ensuring outstanding care for patients. Medical and research societies have organised congresses, courses, e-learning but their work was heavily impacted by the COVID-19 crisis and they need help to continue their important activities.

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The role of academic clinical trials and publicly funded research should be facilitated to ensure important unanswered questions are addressed and medicines meet patients' needs.

While we acknowledge the key role played by the pharmaceutical industry in our health system, there are important research questions that will never be fully answered by a market-driven industry.

- Public funds for clinical trials are key to ensure qualitative, evidence-based medicine, which reflects the needs of European citizens.
- Market access should be supported by sound evidence for the clinical utility of new drugs. Independent research should also focus on treatment optimisation to ensure the most effective, efficient, and safe use of new drugs.
- Support for repurposing studies, especially for old off-patent drugs, is needed to boost therapeutic progress. Academic research plays a crucial role in repurposing studies, as the pharmaceutical industry does not always have the incentive to conduct these studies.
- Guidance documents on clinical trials (in particular ICH E6: Good Clinical Practice) need to be revised to ensure that the guidance is clear and proportionate and does not lead to excessive bureaucratic hurdles for academic clinical trials.

The regulatory framework should be fully adjusted for the use of real-world data and to encourage innovation in health research.

The secure sharing of health data has numerous benefits in biomedical research and can help to accelerate scientific developments. Nonetheless, researchers continue to face practical barriers to the analysis and sharing of health data that should be addressed.

- Guidance on the GDPR application for health research, e.g. through the work of the Joint Action on GDPR compliance for health data, will be essential to ensure a harmonised framework.

Cooperation on Health Technology Assessment is much needed to ensure patients' access to innovation.

For medical and research societies, clinicians and patients, cooperation on HTA has the potential to streamline regulatory procedures, avoid duplication and enhance the quality and equity of healthcare across the EU

- Cooperation on Health Technology Assessment should be facilitated. It is essential that progress on the new regulation on HTA (2018/0018 (COD) is made as soon as possible.

We look forward to continuing the discussions around this important new strategy.