Response from the European Public Health Association (EUPHA) on Pharmaceuticals – safe and affordable medicines (new EU strategy): open public consultation

We welcome the timely effort for an EU strategy for safe and affordable medicines contributing to sustainable healthcare systems, particularly considering the critical aspects it proposes to examine and the given systemic weaknesses made starkly clear by COVID19. We also welcome the emphasis on:

- the digital aspect of access, and
- the role of generics and biosimilars.

We do, however, argue that – beyond the steps proposed – it is within the remit of the European Commission to steer Member States towards a harmonised approach to ensure that shortages will be effectively addressed through EU-wide initiatives.

Creating a reserve of essential medicines

We have witnessed various types of shortages in recent years. Creating a reserve supply of essential medicines, essential medical devices and in vitro diagnostics represents a concrete and urgent need. Where there are no financial incentives (low price) or high complexity (lack of expertise and capacity) to produce these, Member States should step in either directly by producing them or by ensuring mechanisms that are in place to generate incentives to make them worth producing. The role of the European Commission to support such efforts is key, with due consideration to ensure measures are in place for public health security, i.e. manufacturing and supply chain resilience.

Investing in research and development for antimicrobial resistance

We would like to make a special mention of antimicrobial resistance (AMR); a global public health threat remaining largely unaddressed, an area of focus where comprehensive, cross-sectoral and well-funded efforts are needed. A boost in research and development (R&D) efforts are needed to tackle the threat of AMR. The European Commission can help guide Member States collaboration and even go further in terms of direct action, since AMR is a cross-border threat, as highlighted in the AMR Stakeholder Network Roadmap. Furthermore, R&D by academic institutions and small and medium enterprises can be supported by joint financing and balanced allocation across Member States. Assessment of innovation is key to determine its impact and should be transparent.

Common Goods for Health

For essential medicines, but also for any other single good or complex intervention necessary to timely and safely administer the appropriate preventive, diagnostic, therapeutic or rehabilitation intervention, we argue that the Commission and Member States need to consider the definition of Common Goods for Health[1]. This definition highlights the potential need for collective horizon scanning efforts, collective financing agreements, and centralised assessment and evaluation. Joint procurement and negotiation and joint R&D should also be facilitated, where and as needed.

The potential of Health Technology Assessment

We welcome the mention of Health Technology Assessment (HTA). We would, however, argue that HTA has a greater significance. HTA can play a key role to reward true innovation and prioritise true innovation, particularly as the current pandemic highlighted the need to revisit the concepts of value and innovation. Centrally coordinated HTA for key technologies should be reconsidered in the context of timely access to innovative technologies and on the basis of the definition of HTA according to O'Rourke and colleagues (2020)[2]. To benefit from technological advances, we need comprehensive and ethical frameworks and strategies to support the uptake of new technologies. There is, therefore, a concrete need for capacity building to assess such technologies, both from a regulatory and an HTA perspective, with comprehensive investment to ensure the necessary expertise and mechanisms and with strong cross-border cooperation and transparent governance, securing the generation and synthesis of evidence (by design and by default). Considering the importance of HTA to inform evidence-based decision-making, access to innovation and prioritisation and the ongoing Commission's efforts on the legislative proposal for HTA regulation[3], we are surprised to see HTA included under affordability rather than under ensuring greater access and availability of pharmaceuticals.

Cost-effectiveness assessment

EU countries can benefit from collaborative efforts to inform decision of (dis)investment in preventive tools, diagnostics and therapeutics, and in public health interventions, such as screening. Recognising that all health systems face limited resources, it is essential that decisions on innovative medicines are supported by a cost-effectiveness assessment, which would be aided by much greater transparency on development costs.

Strong health information structures

Finally, high-quality, up-to-date population-level data is key, and therefore, the creation of registries and of mechanisms for rapid and safe information exchange should be supported. We note the need for enhanced systems to exchange information and to be able to cohesively synthesize this

[1] https://www.who.int/docs/default-source/health-financing/common-good-for-health/common-goods-for-health-definition.pdf?sfvrsn=b5c9a9f8_2

[2] O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: a milestone in international collaboration. International journal of technology assessment in health care, 36(3), 187-190.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018PC0051

information into evidence-informed recommendations for action. There is also a need to strengthen cross-sectional research on innovation. Both of these key aspects necessitate investment both in research and in health information infrastructures.

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The European Public Health Association, or EUPHA in short, is an umbrella organisation for public health associations in Europe. Our network of national associations of public health represents around 20'000 public health professionals. Our mission is to facilitate and activate a strong voice of the public health network by enhancing visibility of the evidence and by strengthening the capacity of public health professionals. EUPHA contributes to the preservation and improvement of public health in the European region through capacity and knowledge building. We are committed to creating a more inclusive Europe, narrowing all health inequalities among Europeans, by facilitating, activating, and disseminating strong evidence-based voices from the public health community and by strengthening the capacity of public health professionals to achieve evidence-based change.

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