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On 6 July 2020, the CPME Executive Committee adopted the 'CPME Response to the roadmap to the European Commission's Pharmaceutical Strategy' (CPME 2020/054 FINAL).

CPME response to the roadmap to the European Commission's Pharmaceutical Strategy

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues[1].

Europe needs a pharmaceutical strategy that provides citizens with medicines they need at a price they are able to pay.

The strategy must enable the EU to tackle the unaffordability of innovative therapies as well as shortages and other problems with the availability of off-patent medicines. It must ensure the innovation agenda is driven by public health needs, the R&D model is efficient, and safe and effective medicines are timely delivered to the patients. Moreover, it should promote and facilitate Member States' cooperation e.g., in health technology assessment (HTA), price negotiations, contracting and procurement. Last but not least, the forthcoming strategy must make Member States and their health systems better prepared to effectively response to the future public health threats in light of the current pandemic.

Over time, the trust in the pharmaceutical sector and its ability to promote the development of medical innovations while ensuring sustainable access has been eroded. The confidence in how that system works must be rebuilt. Transparency of publicly available information on inputs across the value chain of medicines and other health product must be enhanced, as stated by the WHO Member States i the resolution "Improving the transparency of markets for medicines, vaccines and other health products" from the 2019 World Health Assembly.

European doctors agree with the roadmap that a strategy must be patient-centred. It must serve public interests and properly define the role of pharmaceutical industry as a contributor to public health, this includes improving the translation of research done by smaller innovative biotech companies into commercially exploited innovation.

The roadmap provides a fair overview of the current problems the pharmaceutical system in the EU is confronted with. European doctors provide the following recommendations:

[1]CPME is registered in the Transparency Register with the ID number 9276943405-41.
More information about CPME's activities can be found under www.cpme.eu

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1. Impact of the global context on access to medicines in the EU

CPME finds the roadmap's assessment of the EU's dependence on import of medicines correct. The current model in which certain essential medicinal products are manufactured externally and in just a few production sites leaves Europe exposed.

The EU must gather more data on supply chain risks to establish exactly where their vulnerabilities lie and how its resilience can be strengthened. If needed, the EU should explore regulatory measures or financial incentives to shift the production of essential medicines back to Europe while safeguarding their affordability.

Moreover, the EU's resilience to external emergencies can be increased by stockpiling of medicines within the supply chain also at EU level under coordination of the European Medicines Agency (EMA) allowing for targeted interventions.

The pharmaceutical companies supplying medicines on the EU market should be able to demonstrate that their supply chain is resilient to a variety of shocks, including by not being overly reliant to one country or region, and provide contingency plans to help identify risks early on and promote mitigation measures.

2. Unequal access to medicines and their unaffordability

Even though, as the roadmap notes, pricing and reimbursement are national competences, the EU has a crucial role to play in tackling these issues through:

- engaging with Member States and pharmaceutical industry in a structured exchange on pricing of pharmaceuticals.
    - The current unaffordable prices put equal access for all in jeopardy. Ever increasing prices of innovative treatments threaten the sustainability of healthcare systems and lead to health inequalities.
    - Prices should be based on transparently disclosed R&D costs and the added therapeutic benefit.
- addressing the abuse of the current model of pharmaceutical incentives (e.g., obtaining multiple patents on small changes to a single medicinal product despite the fact they are not truly innovative) in the forthcoming strategy. Incentives should not be based on assumptions but on clinical data that provides evidence for their need. Moreover, a clearer link between investment and reward should be established.
- including pro-public safeguards, such as transparency regarding public contributions and clauses on accessibility and affordability in all kinds of public-private cooperation that includes public funding.
- revising the Orphan Drug Regulation and applying stricter rules for the orphan drug designation, ensuring the reassessment of the orphan designation to take into account extensions and additional authorisations granted for the same medicinal product, and revising the market exclusivity system.

The EU can also contribute to ensuring equal access to medicines in all Member States by subjecting the granting of the marketing authorisation to a commitment on the part of pharmaceutical companies that once authorised, medicinal products will be launched in all EU countries at the same time.

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3. Shortages of medicines

European doctors recognize a crucial role of the EU in prevention of medicine shortages in Europe. In a recently adopted Policy on Medicine Shortages (accessible at CPME website), there are proposed measures that include communicative, organisational, and legislative solutions.

CPME recommends monitoring of medicine shortages at the EU level and establishing tools for information exchange among Member States, as well as adopting widely agreed definitions of medicine shortages and essential as well as innovative medicines.

Moreover, European doctors recognise a need for structural changes. The European Medicines Agency (EMA) should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply.

In addition to the points raised in 1., procurement procedures for medicines should be amended to apply other criteria than price in tendering processes and award contracts to a number of successful tenderers instead of only to one. Furthermore, it should be explored how to expand the possibility of joint procurement of medicines and active pharmaceutical ingredients and their stockpiling at EU level. The roadmap might also discuss whether market integration i.a. in the form of unified ownership of the retail and wholesale levels in the pharmacy-sector has impact on the resilience of deliveries and the robustness of stockpiles.

The roadmap rightly identifies that the reasons of medicines shortages include commercial strategies of pharmaceutical companies, product withdrawals and weak public service obligations. To address them, the current supply and reporting obligations must be strengthened and enforced. European doctors believe the current pharmaceutical legislation should be clarified. Moreover, an early warning system should be introduced obliging all stakeholders in the supply chain to report any shortages at national and at EU level. While additional guidance may be helpful, we believe that only an amendment of Directive 2001/83/EC stating clear obligations and providing for sanctions will be effective.

4. Innovation driven by public needs

European doctors agree with the roadmap's assessment that innovation agenda is not always driven by public health needs. Consequently, the neglected, low-profile areas of "market failures" and unmet medical needs (requiring clearer and stricter definition) are not sufficiently addressed (e.g. antimicrobial resistance (AMR), Alzheimer or dementia).

Firstly, there is a need to agree on a common definition of "innovative medicine" as the one that meets a previously unmet or inadequately met, substantive health need and offers enhanced effectiveness or other incremental benefit relative to existing therapeutic alternatives (see OECD report on Pharmaceutical Innovation and Access to Medicines, November 2018).

Moreover, the Commission should restructure the intransparent R&D model that results in a diminishing rate of real pharmaceutical innovation and high prices. It should ensure that

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transparency and balanced stakeholders' representation are the principles for the agenda-setting and governance of the EU's innovation's initiatives.

Furthermore, conditionalities should be attached to funding for innovation to ensure return on public investment and affordable access to health technologies resulting from them (see 2.).

To achieve the foreseen goals, the Commission must learn from the last two Innovative Medicines Initiatives (IMI) and adapt the way of setting up public-private partnerships in the future.

5. Regulatory framework

European doctors believe that the revision of the procedures for accelerated medicines' development, new means of their assessments, and fast approval and market access must be undertaken cautiously to adequately take patient benefit and safety aspects into consideration.

The Commission must critically review the regulatory procedures accelerated approval by the EMA as such schemes facilitating market entry for medicinal products with limited information on their added therapeutic benefit and safety issues. European doctors note that fast-track medicines' approval has been overused over the last years and argue that conditional marketing authorisation and accelerated assessment should be limited to situations where no other medicinal alternative is available. A strictly regulated framework will be indispensable to safeguard patient safety and health systems.

Moreover, the roadmap discusses improving access to advanced therapy medicinal products (ATMP) and precision medicine. As they hold great medical promises, the Commission should resist the pressure to gain fast-track approvals and do not lower requirements of evidence, putting patients' safety before economic interests.

A critical reflection on which data is relevant for drug development processes needs to be undertaken. Real-world data can provide useful supplementary information in the context of marketing authorisation processes and in particular post approval surveillance activities. However, it is important to have in place appropriate framework ensuring the quality, robustness, reliability and usefulness of collected data. European doctors consider of utmost importance to also guarantee the confidentiality and privacy of patient data. It requires the existence of an appropriate data governance model.

Moreover, CPME shares the Commission's concern regarding the fragmented granting procedures of some pharmaceutical incentives. The supplementary protection certificates (SPCs), as mentioned in the roadmap, are a valid example of how higher medicines' prices associated with the generic competition delays caused by granting of SPCs can hamper equal access.

Lastly, the strategy should also address the industry's manipulation of the patent system by using techniques like "evergreening" to extend exclusivity for drugs and prevent generic competition.

6. Environmental risk and antimicrobial resistance

CPME shares the increasing concerns on the negative effect pharmaceuticals can have on the environment. A right balance between environmental protection and access to medicines needs to be achieved by increasing awareness and promoting prudent use of pharmaceuticals, supporting greener

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manufacturing, and reducing wastage and improving the management of waste. The management of environmental risks associated with production, use and disposal should be addressed in public policies on procurement of medicines and medical equipment.

One potential way to reduce pharmaceutical waste is to extend the expiry dates of certain medicines (particularly small molecules) that are often marketed for much shorter time that their stability would allow for. To proof their actual stability, the duration of these medicines' stability testing should be extended. This could also prove to be helpful with tackling medicine shortages.

The roadmap mentions AMR as one of the major challenges in this domain. Although this assessment is right, the forthcoming strategy should put much greater emphasis on tacking AMR than it is indicated by the roadmap.

The development and spread of AMR have far-reaching consequences. It requires commitment and action from the EU and national policymakers to tackle this public health crisis. It must not be overlooked by the Commission and should prioritized over the next years.

Altogether, the roadmap provides an up-to-date assessment of the problems within the pharmaceutical sector. However, the ultimate success of the forthcoming strategy will depend on how the identified objectives will be translated into concrete actions and then executed. European doctors call on the Commission to propose the strategy that will serve public interests taking into consideration the above proposals.

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