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.

Feedback on the WHO/Europe Access to Novel Medicines Platform

The Standing Committee of European Doctors (CPME) explicitly welcomes the WHO Regional Office for Europe's Access to Novel Medicines Platform initiative to enable direct and open discussions between stakeholder groups to identify actions to improve affordable and equitable access to novel, effective, high-priced medicines in the European Region.

The initiative's proposed strategic aims, especially transparency of the pharmaceutical markets and sustainability of healthcare systems, resonate well with CPME's recent calls surrounding the forthcoming legislative revision of the pharmaceutical legislation in the European Union and the wider policy context. European doctors call on WHO/Europe to identify and leverage, in the context of this initiative, any opportunity for synergies with the work being done at the EU level.

The Oslo Medicines Initiative rightly identified that there is an urgent need to define more clearly the roles and social and ethical responsibilities of the public and the private sectors with respect to research, development and access to medicines. It is commendable that, building on the achievements of the Oslo Medicines Initiative, the Regional Committee decided to establish a formal platform to identify ways to improve access to affordable and effective, novel medicines in Europe.

The work packages proposed as part of building the platform indicate its comprehensive approach to the problem of access to new and high-priced medicines. These are the elements that European Doctors believe are crucial to consider:

First, as rightly proposed there is an urgent need for agreement on what information should be made transparent in accordance with the framework set out in the WHO Transparency Resolution. European doctors believe that Member States should improve transparency and cooperation on pricing of medicines by disclosing net unit prices, which will allow national pricing authorities to make better informed decisions. It could lead to a level playing field for national governments with varying purchasing powers and market sizes, as well as for pharmaceutical companies. Transparency is a precondition to ensure competition and a balanced market. The same applies to the transparency of research and development costs. An effective pricing system should facilitate accessibility but also reflect the public contribution - so taxpayers don't pay twice such as nowadays.

Second, Member States should also realise how joint procurement has benefited their bargaining strength and analyse whether it has been fully exploited by including all possible public interest conditionalities such as transparency in the contracts. Member States should discuss how to improve and expand the scope of joint negotiations. Importantly, a stronger position of different Member States speaking with one voice should be used to demand high transparency standards in future joint undertakings.

Third, when it comes to pricing options, European doctors advocate for a multidimensional approach to pharmaceutical pricing, based on health technology assessment, where various factors are taken into account from the added therapeutic benefits and the economic and social impacts to the ability to pay and access considerations. Medicines should not be perceived as any other commodity. Therefore, the priorities required in pharmaceutical pricing must first concern patient's rights, then be applied to solidarity in care determined by need, and finally concern cost efficiency. The logic that the price of a medicine should equal the costs it saves society should be strongly opposed.

Fourth, the generation of meaningful comparative data on novel products is essential. This could happen through the harmonisation of the designs, by choosing reasonable endpoints and outcomes of clinical trials, early dialogues between all stakeholders, encouraging randomised controlled trials with active comparators, and explicitly proven added therapeutic benefit in pricing and payment decisions. This could help avoiding the obvious risk that there is no consistent link between a medicine's price and the associated medical benefit. European doctors would like to highlight the importance of post-marketing studies as a main source of evidence for clinical decision making.

Lastly, given that the public co-creates and is a major investor in health technologies, Member States should take an active role in defining directions for health innovation to create a system that is aligned with medical and social needs, rather than leaving it to be driven by commercial interests alone.

WHO/Europe's leadership in advancing collaboration to ensure patient access to novel medicines is strongly supported by European doctors who remain committed to contributing to a sustainable and balanced system that also serves better the public interest. This initiative is of particular importance as during the last decade the current research and development (R&D) system has been biased towards high revenue generating diseases, leading to an increasing gap between so-called innovative medicines and real unmet medical needs.