CPME statement on the Oslo Medicines Initiative

The Oslo Medicines Initiative
Consultation with non-State actors
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European doctors explicitly welcome the WHO/Europe's and Norway's initiative to develop "*a new vision for collaboration between the public and private sectors*" in order to allow patients better access to novel and hopefully effective and safe medicines.

The initiative's ambition - to reconcile the patients' right to reasonably priced medicines with the pharmaceutical industry's profit-driven business model - is fully supported by European doctors' recent call to restore balance in the pharmaceutical sector on which forthcoming legislative and policy changes in the EU are targeted.

The initiative correctly observes that the increasing number of novel medicines entering the market frequently with high prices and uncertain clinical benefits, poses a great challenge for the sustainability of health budgets. It also affects doctors' and patients' ability to choose the appropriate treatment.

This initiative rightly places a special emphasis on collaboration as the best possible way to address this issue. Timely access to effective, safe and affordable medicines depends on close cooperation among Member States as well as between the public and private sectors.

In my today's short statement, I will briefly focus on three topics where strengthened cooperation among Member States and between the public and private sectors can be particularly beneficial: firstly, the generation of comparable and robust data on new medicines, secondly, their pricing and procurement, and thirdly, health innovations that are accessible, affordable and really meet patient needs.

At first, comparable and robust data are critical for informed marketing authorisations, for assessing the potential benefits and harms of new medicines against existing ones, for making pricing and reimbursement decisions and, finally, for allowing doctors and patients to make the best individual choice of treatment.

Regulatory agencies, HTA bodies and payers working together and supported by patients, healthcare professionals and pharmaceutical companies can lead to the generation of meaningful comparative data on new products. 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. Thus, the obvious risk that there is no consistent link between a drug's price and

the associated medical benefit can be avoided. During the last few years, the challenges of the combination "accelerated approvals and high-priced drugs with uncertain clinical benefit" – for example in the field of cancer drugs – were obvious. Therefore, postmarketing studies as a main source of evidence for clinical decision making are of paramount importance.

Secondly, 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. An effective pricing system should facilitate accessibility but also reflect the public contribution - so taxpayers don't pay twice such as nowadays.

Member States should also draw conclusions from the experience gained during the COVID-19 pandemic, 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.

Thirdly, when it comes to creating a more beneficial cooperation with the private sector to provide patients with affordable medicines that bring added therapeutic benefits, the current system of health innovation should be reshaped. 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.

Moreover, all forms of public investment in the R&D process should be subject to concrete commitments. Medicines benefiting from a centralized marketing authorization at EU level should be launched in all Member States at the same time.

WHO/Europe's and Norway'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.