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The EU has an opportunity to restore the balance in the pharmaceutical sector: let's not miss it

As the revision of the EU's General Pharmaceutical legislation enters the final negotiations between the EU institutions, European doctors reaffirm that the EU cannot miss the opportunity to rebalance the pharmaceutical sector for the benefit of patients and healthcare systems.

CPME President Dr Ole Johan Bakke said "The revision of the EU's pharmaceutical legislation is a once in a generation opportunity to rebalance the sector. European doctors call on EU leaders to ensure that the EU's pharmaceutical system serves and delivers for patients."

"We must guarantee that all EU citizens have equitable access to the medicines they need. This means ensuring filing for pricing and reimbursement of medicines in all Member States."

Regarding the development of novel antimicrobials, European doctors agree that a new market model is needed. However, we have strong reservations about the proposed transfer exclusivity extension voucher, which could result in a significant extension of the protection period for other more expensive medicines, for example cancer treatments. Safeguards should be in place to avoid misuse of the voucher, in line with the European Parliament's position, namely, conditions for revocation, linkage to WHO pathogen lists, and milestone payments. We are also concerned of a scope-creep where the introduction of the voucher may lead to similar mechanisms being demanded for other types of medicine in future, opening a Pandora's box resulting in higher costs for healthcare systems.

We reiterate that electronic product information (ePI) should never replace the paper version included in medicine packets. CPME calls on governments and national competent authorities to maintain this complementarity between paper leaflets and electronic version in the medicines packages.

We also stress that ePI must not compromise patient privacy, and third-party links must not store personal information. There is the utmost need to ensure that patient data is not collected in patient profiles and used for commercial purposes or promotional activities. ePI should only

be accessed from trusted sources (e.g. EMA or National Competent Authorities websites) and must be supported by a detailed cybersecurity protocol.

The Council's new proposal on redispensing of medications, would allow pharmacies to collect and redispense certain unused prescription medicines. There are serious concerns in on feasibility, liability and safety of such practices. CPME stresses that the focus should be rather on better dispensing policies, with unit-per dose dispensing systems in both hospital and community pharmacy settings.

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.