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On 25 April 2021, CPME adopted its 'response to the evaluation roadmap on the revision of the general pharmaceutical legislation' (CPME 2021/056 FINAL).

CPME response to the evaluation roadmap on the revision of the general pharmaceutical legislation

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.

The Pharmaceutical Strategy set the right course of action towards ensuring that patients have equal and continuous access to old generic and novel advanced medicines at affordable prices.

This ambition is fully supported by European doctors calling for restoring balance in the pharmaceutical sector.

The evaluation roadmap on the revision of the general pharmaceutical legislation correctly observes that, in achieving this objective, the Directive 2001/83/EC and Regulation (EC) No 726/20042 need to be adapted based on the experience gained over the last years and reflecting technological developments.

Health innovation and affordability

European doctors support reviewing the system of incentives based on intellectual property rights (IPR) and urge the Commission to explore alternative models that encourage the development of relevant health technologies, such as delinkage.

To improve the affordability of medicines, the legislation's revision should address the abuse of the IPR system to delay market entry of generics and biosimilars and ensure that all forms of rewards and public investment in the R&D process should be made conditional on concrete commitments.

Availability and medicine shortages

To address inequalities in access to medicines, the revised legislation should restrict deferred market launches. For this purpose, the centralised marketing authorisation should be linked to a commitment on the part of pharmaceutical companies, i.e., once authorised, medicinal products have to be launched in all EU countries at the same time.

Securing the supply of medicines across the EU and avoiding shortages is rightfully one of the revision's main objectives. This requires targeted legislative, organisational and communicational changes. It

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should not be overlooked that medicine shortages are often the result of profit-oriented decision-making on the part of the pharmaceutical industry. The Commission therefore correctly notes the need to reinforce the obligation of continuous supply. To this end, the Directive 2001/83/EC needs to be clarified i.e., introduce enforcement mechanisms and sanctions (e.g., license withdrawal) to hold marketing authorization holders accountable.

Antimicrobial resistance and environmental protection

European doctors support defining new approaches to tackle AMR by improving the prudent use of antibiotics and supporting the development of new ones. Moreover, in line with the roadmap, CPME calls for striking the right balance between access to medicines and environmental protection e.g., by including increasing environmental requirements for all actors in the pharmaceutical sector.

Data on medicinal products and accelerated approval procedures

European doctors recognise the importance of patients' timely access to new medicines. However, the increasing number of advanced medicinal products entering the market with high prices and limited information on their added therapeutic benefits and safety issues poses a great challenge for the sustainability of health budgets and affects doctors' and patients' ability to choose the appropriate treatment.

Rather than examining ways to further accelerate medicinal product authorization, the Commission should critically review the current accelerated approval procedures, which are overused. For that purpose, the term "unmet medical need" should be defined more narrowly.

Any revision of the regulatory procedures and approaches to the assessment of scientific evidence must be undertaken cautiously in order to adequately take patient benefit and safety aspects into consideration.

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