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Brussels, 15th of December 2022

Subject : joint letter for a pharma revision promoting equal access to high quality and affordable medicines in Europe

Dear Mrs Commissioner,

We support the upcoming revision of the European pharmaceutical legislation towards better access for patients to **high-quality, affordable and available medicines**. The new legal framework should, on the one hand, **promote sustainability, innovation and competitiveness** and, on the other hand, **ensure accessibility and affordability of medicines**. Better access for patients to medicines with added therapeutic value depends on achieving these twin goals.

We believe, the following approach should be pursued when revising the regulatory framework(s) on pharmaceuticals (and expanded to other health technologies):

First and foremost, the European pharmaceutical ecosystem should promote **access to the best possible treatment for all patients**. On the one hand, this means ensuring that medicines come to the market with robust proof of quality, safety and efficacy, where possible by means of randomised controlled trials and upon timely pre- and post-launch evidence submission. On the other hand, it means creating a regulatory framework that not only incentivises innovation but also promotes (early) competition of generics and biosimilars, as a way to ensure affordable access. Promoting access also means maintaining effective therapies on the markets, via appropriate medicine shortages prevention and mitigation measures and sanctionable obligations anticipating market withdrawals.

Second, the **incentives system should be carefully assessed, balanced and targeted**, both in terms of regulatory/patent protection and access to data for research and development (R&D) purposes. Misguided incentives led by purely economic/commercial purposes must be eliminated/avoided. Beyond incentives, marketing authorisation should be granted under well-defined conditions e.g. in terms of evidence and transparency requirements, steering research towards targeted therapeutic areas especially where an unmet medical/societal need exists, and accordingly require Europe-wide submission of pricing and reimbursement applications. Otherwise, unconditional incentives may spur innovation that does not reach patients and ultimately exacerbate health inequalities and worsen access delays.

Third, when revising the EU pharmaceutical legislation, **the sustainability of European healthcare systems should be duly preserved and take into account the environmental impact of international production**. Balancing rewards with adequate conditionalities and upon safeguards on transparency & return on investment should remain the guiding principle. The regulatory framework should be fit-for-purpose to empower decision-makers along the product's lifecycle in their respective remits to authorise, assess and reward evidence-based treatments at a fair price, while promoting price transparency and affordability through generics and biosimilars competition.

Yours sincerely,

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