Advancing patients' access to medicines in the pharmaceutical legislation

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In the context of the ongoing discussions on regulatory data protection periods in the revision of EU pharmaceutical legislation, **the European Patients' Forum (EPF) is concerned that proposals to extend the current regulatory data protection period (RDP) and to introduce disproportionate RDP incentives risk further reducing patients' access to medicines.**

We are concerned about the emergence of a narrative that extending RDP periods would somehow benefit patients. This is not the position of EPF or our members. In our July 2023 paper, we called on legislators to **strike the right balance** between incentivising patient-centred innovation and ensuring equitable access to medicines across Europe. In our position paper, we supported the principle set out by the European Commission, of a lower baseline RDP along with conditional incentives for supporting **earlier patient access**, as a way of supporting broader public health objectives.

The current system is failing millions of people who lack access to new medicines. Unacceptable inequalities in access remain within and between EU countries. By increasing RDP periods, the legislators would commit to an increase in spending on medicines, but without **mechanisms to improve and expand patients' access to clinical trials, approved medicines, and needs-driven innovation.**

When discussing ways to incentivise pharmaceutical research, we call on decision-makers to assess how their proposals contribute to making the five As of access a reality for all patients across Europe:

- **Availability**: the medicine needs to be present on the market; this applies both to new medicines and to generics and biosimilars, which are essential alternatives for many patients
- **Affordability**: patients should not suffer financial hardship as a result of seeking treatment and financial trade-offs should not impact patients' ability to receive the treatment they need
- **Adequacy**: the medicine should be safe, of high quality and effective
- **Appropriateness**: the medicine must meet patients' needs, as defined by them
- **Accessibility**: the medicine should be distributed through reachable channels, without geographical or time barriers

The review of the pharmaceutical legislation is a once-in-a-generation opportunity to get it right for patients and put them at the heart of the EU's regulatory system for medicines. We will continue to engage with decision-makers to find balanced policy solutions that truly improve patients' access to the medicines they need across the EU.

ABOUT EPF

EPF is an umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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