“Adaptive Licensing” or “Adaptive Pathways”: Deregulation Under the Guise of Earlier Access

POLICY BRIEF

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Executive Summary

Adaptive licensing” (AL), also called “adaptive pathways” (AP) or Medicines Adaptive Pathways to Patients (MAPP), is described as “(…) a prospectively planned, flexible approach to regulation of drugs and biologics”. Presented as a new “concept” and even as a new paradigm”, it aims to allow medicines onto the market faster, based on lower evidence requirements than under a conventional marketing authorisation. The main claimed benefits of AL are that patients will gain “earlier access” to new medicines and that companies will benefit from “an earlier revenue stream (…) and less expensive and shorter clinical trials”.

“Adaptive pathways” raise numerous concerns from a public health perspective. The organisations that endorse this statement have closely monitored developments in EU pharmaceutical regulation for many years and put forward a critique of the “adaptive pathways
concept”.

First, we highlight the importance of maintaining the requirement for solid efficacy evidence before a medicine is approved for marketing as the cornerstone of pharmaceutical regulation. The requirement for pre-market efficacy and safety evidence is an important health protection measure, as it prevents harmful exposures unless there is solid scientific evidence supporting a potential benefit to health. The marketing authorisation procedure emerged as a response to a series of drug-induced disasters and has been applied for nearly 50 years. There have been several attempts, particularly over the last decade, to expand the use of “premature” and “accelerated” approvals to all new drugs.

Second, we outline the main lessons learnt from current initiatives providing faster patient access to new medicines. This overview includes a short insight into the new business paradigm of the pharmaceutical industry—the “nichebuster” model—which contributes to greater pressure on health authorities to reduce evidence requirements for marketing approval and price-setting.

Third, our critical assessment of the adaptive licensing/pathways "concept" reveals potential consequences to patients' safety by shifting, even more, the burden of evidence from pre-marketing to post-marketing. Post-authorisation commitments are often not honoured. This approach can lead to widespread exposure and population harm before a medicine is removed
from the market. Implementing adaptive pathways could lead to a situation where premature marketing authorisations become the rule, even when no genuine public health need exists, therefore putting EU citizens' health unnecessarily at risk. Even if a public health need is identified, lowering requirements for efficacy means that products that are unlikely to meet that need will still be introduced.

The European Medicines Agency's (EMA) pilot project, launched in March 2014 has not been endorsed by the European Parliament and Council. It undermines the democratic process as it aims to change current practices without a proper discussion or legal basis. It paves the way for the deregulation of marketing approval procedures and increases industry's control over other
healthcare actors, such as health technology assessment (HTA) bodies, prescribers and patients.

Finally, faster market access and escalating drug prices are not proper incentives for real drug innovation. On the contrary, to ensure access to medicines for unmet medical needs, we offer
pragmatic recommendations to:

- Demand a robust evaluation of new drugs prior to marketing authorisation (introducing the demonstration of added therapeutic value);
- Ensure that conditional and expedited approval mechanisms are only used in duly justified circumstances (e.g., when there is a true unmet medical need);
- Uphold the rights of EU citizens to obtain compensation from drug- or medical device-induced harm;
- Ensure greater transparency of clinical data, including pharmacovigilance data from regulatory agencies;
- Reinforce the independence of drug regulatory agencies from corporate influence and funding;
- Support needs-driven R&D models as an alternative to corporate-driven R&D.

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