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"Adaptive pathways": EMA' s dangerous plan

A joint briefing paper endorsed by HAI Europe, ISDB, Institut Mario Negri, Medicines in Europe Forum, Nordic Cochrane Centre and Wemos is available at english.prescrire.org/Advancing healthcare policy/A recap of actions in 2015.

Abstract

- **The aim of the "adaptive pathways" proposed by the European Medicines Agency (EMA) is to shorten the process for bringing drugs onto the market, by relaxing the requirements for proof of efficacy and safety that apply to conventional marketing authorisation (MA) procedures.**
- **The alleged benefits of adaptive pathways are that patients would have early access to new drugs and pharmaceutical companies' revenues would increase as a result, making the European market an attractive one.**
- **Yet many accelerated or compassionate-use MA procedures are already in place to provide early access to new drugs for patients with serious conditions and in whom any existing treatments have failed.**
- **The principle of adaptive pathways is based on evaluation of drugs after rather than before authorisation. Yet MAs granted subject to continued evaluation already exist, and pharmaceutical companies rarely fulfil their obligations concerning these post-authorisation studies.**
- **If adaptive pathways are introduced, it could lead to a situation in which MAs granted on the basis of very limited evaluation become the norm, even when no pressing public health need exists.**
- **The authorisation of drugs throughout the European Union after limited evaluation places the patients who take them at unnecessary risk. These drugs could cause considerable harm before their adverse effects are finally recognised and their MAs withdrawn.**
- **The EMA's adaptive pathways pilot project, launched in March 2014, was not submitted to the European Parliament or the Council of Europe for approval. By trying to change current practices without any prior debate or valid legal basis, it undermines the democratic process.**
- **It paves the way for the deregulation of MA procedures and strengthens the pharmaceutical industry's control over health technology assessment bodies, prescribers and patients.**
- **As of 2016, the main barrier to access to new drugs is not how long it takes drug regulatory agencies and health technology assessment bodies to evaluate them, it is their price.**

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