PRIME Example of How EMA is Pushing for Accelerated Market Approvals

(Joint consultation response by HAI, ISDB, MiEF, Nordic Cochrane Centre and Wemos)

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Health Action International, International Society of Drug Bulletins, Mario Negri Institute for Pharmacological Research, Medicines in Europe Forum, Nordic Cochrane Centre and Wemos are glad to contribute to the EMA public consultation on the Draft Reflection paper on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines
(PRIME).

In this joint response, we highlight concerns with current attempts to weaken marketing authorisation requirements in the EU, most notably through the EMA's adaptive pathways project. The PRIME scheme appears to be a complementary move to entrench the provision of confidential, customised advice to pharmaceutical companies in the regulatory system for expedited approval and coverage of new, expensive medicines which as evidence suggests will rarely bring therapeutic advance but often safety concerns.

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