PRESS RELEASE

18 May, 2017 *For immediate release*

Proposed Changes to EMA's Access to Documents Policy Fall Short on Proactive Disclosure

BRUSSELS—The European Medicines Agency's (EMA) proposed amendments to its access to documents policy do not sufficiently ensure comprehensive access to documents, say medicines policy watchdog organisations, Health Action International, the International Society of Drug Bulletins, NoGracias, the Nordic Cochrane Centre and Prescrire.

In a joint public consultation response to the EMA, the Coalition raised concerns that under the revised policy, many documents, including those used to inform key decisions on medicinal products, would only be disclosed by the EMA upon written request—and would likely be redacted for commercial confidentiality.

"Public access to the EMA's, clinical data, decision-making and corporate documents is critical for strengthening accountability and trust in its regulatory processes," said Ancel.la Santos Quintano, senior policy advisor with Health Action International. "While we commend the EMA for clarifying its approach to document disclosure, we regret that the revised access to documents policy falls short on proactive disclosure."

To address concerns about proactive disclosure of documents, the Coalition recommended that the EMA establish a comprehensive public register of all its documents. It also urged the EMA to prioritise health over commercial interests at all times.

The Coalition also flagged issues with the EMA's current 'access to documents on request' system. Research institutes and civil society organisations have experienced long delays and cumbersome administrative processes in accessing documents.

"Requests by independent researchers are particularly relevant from a public health perspective," said Pierre Chirac, editor of Prescrire. "We strongly encourage the EMA to increase resources so it can more efficiently handle these requests."

The EMA's access to documents policy was implemented in 2010 to comply with Regulation (EC) No 1049/2001. The Regulation gives citizens the right to access documents from European Union institutions and other agencies.

For further information or interview requests, contact:

Ancel.la Santos Quintano
Senior Policy Advisor
Health Action International
Email: ancel.la@haiweb.org
Phone: +32 2 486 0179

Pierre Chirac
Editor
Prescrire
Email: pierrechirac@aol.com

-END-